UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL DOCKET NO. 1456 Master File No. 01-CV-12257 Subcategory Case No. 06-CV-11337
THIS DOCUMENT RELATES TO: *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.*, No. 06-CV-11337-PBS *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al.*, No. 05-CV-11084-PBS; and *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.*, No. 07-CV-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

DEFENDANTS ABBOTT LABORATORIES, INC., DEY, INC., DEY, L.P, DEY L.P., INC., AND BOEHRINGER INGELHEIM ROXANE, INC.'S COMBINED RESPONSE TO THE UNITED STATES' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS COMMON TO ALL DEFENDANTS

PRELIMINARY STATEMENT

Defendants Abbott Laboratories Inc. ("Abbott"), Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey") and Boehringer Ingelheim Roxane, Inc. (f/k/a Roxane Laboratories, Inc.) ("Roxane") (collectively, "Defendants") submit this response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common To All Defendants (Dkt. No. 6316). To the extent a statement of fact asserted by the United States is undisputed, it is undisputed solely for the purposes of the United States' Motions for Partial Summary Judgment against Abbott, Dey, and Roxane, and the United States' Oppositions to Abbott, Dey, and the Roxane's Motions for Partial Summary Judgment. Defendants reserve the right to modify or supplement their responses as necessary. Defendants reserve the right to object to the relevance of any and all facts asserted by the United States.

In addition to these Responses, Defendants' Statement of Additional Material Facts Under Local Rule 56.1, filed contemporaneously herewith, sets forth other material facts that are necessary for this Court to determine the United States' Motions for Partial Summary Judgment Against Defendants.

DEFENDANTS' RESPONSES TO PLAINTIFFS' STATEMENT OF ALLEGED FACTS[1]

1. Medicare is a federally-funded health insurance program for people age 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant). 42 U.S.C. § 1395 *et seq.* Medicare Part A helps cover inpatient care in hospitals, including critical access hospitals, hospice, skilled nursing facilities, and some home health care. 42 U.S.C. §§ 1395c-1395i-4. Medicare Part B helps cover doctors' services and outpatient care. 42 U.S.C. §§ 1395j to 1395w-4. It also covers some other medical services that Part A does not cover, such as some of the services of physical and occupational therapists, and some home health care not covered by Medicare Part A. Medicare Part B also covers certain drugs. 42 C.F.R. §§ 405.517, 414.701, 410.26.

DEFENDANTS' RESPONSE: Undisputed, although the statutory cites do not support the propositions for which the Government offers them. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006).

2. Since the early 1990s, Medicare Part B has typically paid for covered drugs using average wholesale prices (AWP) published in the Red Book. (Common

[1] In Defendants' Combined Response to the United States' Local Rule 56.1 Statement of Undisputed Facts Common to all Defendants, the various sources cited by Defendants are abbreviated as follows: United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants ("US-SOF"); United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey ("US-Dey-SOF"); Concise Statement of Undisputed Material Facts in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment ("Dey SOF"); The Roxane Defendants' Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment ("Roxane SOF"); Abbott Laboratories Inc.'s Rule 56.1 Statement of Additional Facts That Preclude Summary Judgment in Favor of the Government ("Abbott SOF"); Declaration of Sarah L. Reid in Support of Defendants' Common Opposition to Plaintiffs' Motion for Summary Judgment ("Reid Common Decl."); Declaration of Sarah L. Reid in Support of Dey's Opposition to Plaintiffs' Motion for Partial Summary Judgment ("Reid Opp. Decl."); Declaration of Sarah L. Reid in Support of Dey, L.P., Dey, Inc., and Dey L.P., Inc,'s Motion for Partial Summary Judgment ("Reid Decl."); Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Individual Local Rule 56.1 Statement in Opposition to the United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey ("Dey Resp. to US-Dey-SOF"); Common Declaration of George B. Henderson in Support of Motions for Partial Summary Judgment ("Henderson Common Decl."); Combined Memorandum of Defendants Abbott Laboratories, Inc., Dey, Inc., Dey, L.P, Dey L.P., Inc., and Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc. in Opposition to the United States' Cross-Motions for Partial Summary Judgment ("Defs. Comb. Memo."); and Defendants Abbott Laboratories, Inc., Dey, Inc., Dey, L.P, Dey, L.P., Inc., and Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc.'s Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent to the United States' Motions for Partial Summary Judgment Against Defendants ("Defs. Comb. SOF").

Declaration of George B. Henderson in Support of Motions for Partial Summary Judgment (hereinafter, Henderson Common) Exhibit 1)

DEFENDANTS' RESPONSE: Undisputed that since 1991 Medicare Part B has typically paid for drugs using AWPs published in drug pricing compendia, and that Medicare Carriers typically relied on the Red Book compendia. Disputed, however, that Medicare has used only the AWPs published in Red Book, as that is not supported by the citation the Government offers or by the evidence in the record. The Medicare regulations instructed Medicare carriers to consider all pricing compendia, including Red Book, First Databank, and Medispan. (*See* Roxane SOF ¶ 163 (undisputed); Reid Common Decl., Ex. 10; Reid Common Decl., Ex. 1, at 116-19; Reid Common Decl., Ex. 2, at 481-82.) The document provided by the Government evidences only that by 1994 the Palmetto Durable Medical Equipment Regional Carrier ("DMERC") had limited its review exclusively to Red Book.

3. Since at least the 1970s, Medicare Part B has covered items of durable medical equipment (DME), including drugs used in conjunction with DME. 42 C.F.R. §§ 414.200, 414.701.

DEFENDANTS' RESPONSE: It is undisputed that Medicare Part B currently covers durable medical equipment and drugs affiliated with such equipment, and has provided similar coverage throughout the relevant period, but Defendants dispute that this coverage has existed since at the least the 1970s as that fact is not supported by the citations to the Code of Federal Regulations. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants further dispute that this paragraph is material to any of the Government's claims against them. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005).

4. Medicare Part B classifies and pays for covered drugs through a coding system called the Healthcare Common Procedure Coding System (HCPCS). Medicare assigns individual HCPCS codes for most drugs. These codes have usually included a prefix of ”J” or “K.” One HCPCS code may cover a generic drug manufactured by a variety of manufacturers. The HCPCS codes are used in the determination of allowable amounts, and Medicare Part B payments for most covered drugs are made on the basis of HCPCS codes. (Henderson Common Exhibit 2; Henderson Common Exhibit 3 (Declaration of Carolyn Helton (hereinafter, Helton Decl.), ¶ 7)

DEFENDANTS' RESPONSE: It is undisputed that Medicare Part B classifies and pays for drugs through the HCPCS system, that some of these codes include “J” or “K” prefixes, that most drugs have individual codes, that the codes cover drugs manufactured by a variety of manufacturers, and that Medicare Part B pays most covered drugs based on these codes.

Disputed, however, that the Government has cited proper evidentiary support for the facts set forth in this paragraph. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants object to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

5. The Medicare program is administered by the Department of Health and Human services through the Centers for Medicare and Medicaid services (CMS, formerly known as the Healthcare Financing Administration). CMS uses fiscal intermediaries, also called carriers, to perform bill processing and benefit payment functions for the Medicare program. 42 U.S.C. § 1395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421 .5(b). Most providers of services (such as hospitals, skilled nursing facilities, home health care providers) submit bills to these intermediaries, which determine whether the services are covered under Medicare and determine correct payment amounts. 52 Fed. Reg. 37526,37527 (October 7, 1987).

DEFENDANTS' RESPONSE: Defendants dispute the statement that most providers “determine correct payment amounts” or that the Medicare carriers consistently followed statutory mandates or regulations and guidance from CMS as contradicted by the factual record

in this case and unsupported by the regulations cited by the Government. (*See* Roxane SOF ¶¶ 163-224.) Undisputed that the contractors act "on behalf of CMS" in making payments on claims under Medicare Part B, but disputed that the cited regulation makes this statement or that the carriers consistently followed HCFA/CMS directives or regulations. Defendants do not dispute that CMS administers the Medicare program through its regulations or that it utilizes carriers in doing so.

6. In 1993, HCFA established four Durable Medical Equipment Regional Carriers (DMERCs) and assigned DME claims administration functions to those carriers. 58 Fed. Reg. 60789 (November 18, 1993); 57 Fed. Reg. 27290 (June 1 8, 1992). Each DMERC performs DME claims administration functions for a region of the country. 42 C.F.R. § 421.210. During the pertinent time period the four regional DMERCs were known as Travelers Insurance Company/HealthNow (DMERC Region A)[2]; AdminaStar Federal (DMERC Region B); Palmetto GBA (DMERC Region C); and CIGNA (DMERC Region D). 58 Fed. Reg. 60789 (November 18, 1993).

DEFENDANTS' RESPONSE: Undisputed, except that any contention that the Medicare carriers consistently followed statutory mandates or regulations and guidance from CMS is disputed and is contradicted by the factual record in this case and unsupported by the regulations cited by the Government. (*See* Roxane SOF ¶¶ 163-224.)

7. During the relevant time period, HCFA and CMS periodically issued program memoranda to the carriers and DMERCs providing instructions concerning the administration of the Medicare program. (Henderson Common Exhibit 4 (10/1 1/2007 Niemann Dep.), at 365:9-365:22; Henderson Common Exhibit 5 (4/25/2007 Tawes Dep.), at 435:4 - 435:6)

DEFENDANTS' RESPONSE: Undisputed, except that any contention that the Medicare carriers consistently followed statutory mandates or regulations and guidance from

[2] The DMERC-A contract was initially awarded to Travelers Insurance Company. Through a series of corporate transactions, United Healthcare became the successor-in-interest to Travelers and served as the DMERC until September 2000, when HealthNow was awarded the DMERC contract for Region A. 70 Fed. Reg. 9232 (February 25, 2005).

CMS is disputed and is contradicted by the factual record in this case. (*See* Roxane SOF ¶¶ 163-224; Dey Resp. to US-Dey-SOF ¶ 205; Dey SOF ¶¶ 171-72.)

8. Prior to January 1, 1992, there was no specific regulation or statutory provision that governed Medicare payments for drugs, instead, the government set payment limits based on the overarching Medicare Part B provisions, limiting payments under Part B to a "reasonable charge." *See* 42 U.S.C. §§ 13951, 1395u(o). As for "reasonable charge," Congress wanted Medicare payments to be limited by what a physician "customarily" charged patients for a particular service or the "prevailing" charges for a service in a given locality. S. Rep. No. 404, 89th Cong., 1st Sess., reprinted in 1965 U.S.C.A.A.N. 1943, 1984-85.

DEFENDANTS' RESPONSE: Undisputed. Defendants, however, dispute that this paragraph is material to any of the Government's claims against them. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). Furthermore, the statement "Congress wanted Medicare payments to be limited by what a physician 'customarily' charged" is unsupported by the Government's proffered evidence. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). The citation is limited to a quote that is taken out of context. Also, the record is replete with evidence of different congressional goals such as access to care, cross subsidization for inadequate dispensing fees, ensuring adequate reimbursement, and other policy goals. It is undisputed that prior to 1992, the statute cited allowed Medicare payments based on "a reasonable charge."

9. HHS promulgated its first Medicare drug payment regulation in 1991. The regulation stated:

> § 405.517 Payment for drugs that are not paid on a cost or prospective payment basis.
>
> (a) Applicability. Payment for a drug that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies includes a drug furnished incident

> to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter.
>
> (b) Methodology. Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.
>
> (c) Multiple-Source drugs. For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.
>
> 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991).

DEFENDANTS' RESPONSE: Undisputed.

10. The surveys contemplated by subsection (b) were not completed. (Henderson Common Exhibit 6 (6/20/2007 Vito Dep.), at 338:4 - 339:15)

DEFENDANTS' RESPONSE: Undisputed that surveys identified in subsection (b) were not completed, although the testimony cited by the Government does not support that the surveys contemplated by the regulation were not completed. It is unclear that the witness is referring to those particular surveys. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006).

11. From 1992 through December 31, 1997, Medicare paid for Part B covered multiple-source drugs based on the lower of the provider's billed charge or the median AWP of the generic forms of the drug. 56 Fed. Reg. 59502, 5962 1 (November *25*, 1 99 1); (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 4, 13)

DEFENDANTS' RESPONSE: Undisputed that this was the payment methodology set forth in the Federal Register. Disputed, however, that Medicare paid for all drugs in this fashion. Defendants further state that Medicare also paid a dispensing fee. (*See* Dey SOF ¶ 205.) Defendants object to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

12. From January 1, 1998, until December 31, 1998, Medicare based its reimbursement for all generic forms of a drug at 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998).

DEFENDANTS' RESPONSE: Undisputed that this was the payment methodology set forth in the Federal Register. Disputed, however, that Medicare paid for all drugs in this fashion. Defendants further state that Medicare also paid a dispensing fee. (*See* Dey SOF ¶ 205.)

13. From January 1, 1999, through December 31, 2003, the Medicare paid for Part B covered multiple-source drugs based on (a) the amount submitted by the provider on the claim, or (b) 95 percent of the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. That median then served as the basis for reimbursing for all drugs within a HCPCS code, regardless of manufacturer. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1999-2004); (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 3, 13)

DEFENDANTS' RESPONSE: Undisputed that this was the payment methodology set forth in the Federal Register. Disputed, however, that Medicare paid for all drugs in this fashion. Defendants further state that Medicare also paid a dispensing fee. (*See* Dey SOF ¶ 205.) Defendants object to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

14. According to testimony from the former CMS Director of Payment Policy, comparisons between the Veterans Administration (VA) drug purchasing data and Medicare reimbursement were not useful to CMS officials because CMS, unlike the VA, was not purchasing drugs directly from manufacturers. In addition, the VA purchased drugs in much larger volumes than Medicare providers and could leverage discounts directly from manufacturers. (Henderson Common Exhibit 7 (4/23/ 2007 Booth Dep.), at 43:20-44:5, 212:20 -213:18, 216:17 - 218:12); Henderson Common Exhibit 8)

DEFENDANTS' RESPONSE: Disputed. The witness did not testify that comparisons between the VA drug purchasing data and Medicare reimbursement "were not useful to CMS

officials." That characterization is unsupported by the testimony the Government cites. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006).

15. The pricing analyst for CIGNA, the DMERC for Region D, during the relevant time was Carolyn Helton. She determined the allowable amounts for DME drugs on behalf of CIGNA during the time in question. The source of CIGNA's pricing information was the Red Book, unless that publication did not publish the information needed for a particular product. (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 9, 10, 18)

DEFENDANTS' RESPONSE: Undisputed that Ms. Helton served as the CIGNA DMERC pricing analyst, that she determined the allowable amounts for CIGNA, or that CIGNA generally used the Red Book as its source for pricing information despite permission from HCFA/CMS to use other compendia (*see* response to ¶ 2, *supra*), but the Government does not cite proper evidentiary support for these facts. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants object to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

16. To determine the median AWP of the generic sources of a drug, Ms. Helton used the Red Book to find the products that fit within the narrative description of the pertinent HCPCS code. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 10) She recorded the product information, including the published AWPs, in an array (or she updated a pre-existing array), and converted the published package AWP price in the Red Book to a per-unit price. If there was only one NDC with a published AWP in the array, she selected that price as the median. If there was an odd number of NDCs in the array, she selected the middle NDC and its corresponding price. If there was an even number of NDCs in the array, she took the average of the middle two NDCs' prices to achieve a median. (*Id.*, ¶ 11)

DEFENDANTS' RESPONSE: Undisputed that Ms. Helton generally used Red Book as her source of prices despite permission from HCFA/CMS to use other compendia (*see* response to ¶ 2, *supra*), and undisputed that in general this paragraph describes how Cigna constructed pricing arrays and calculated the median, but the Government does not cite proper evidentiary

support for these facts. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants object to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

17. On or around September 8, 2000, CMS sent Program Memorandum Transmittal AB-00-86 to Medicare Part B carriers, including the DMERCs, providing them with alternative wholesale price information developed jointly by the Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU). (Abbott Ex. AP; Roxane Tab 118; Reid Decl. Ex. 1 81) The price information covered 32 different drugs, including some of those at issue in the instant cases, compiled mainly from wholesaler catalogs. (*Id.* at 1) (The parties have referred to the alternative AWPs as the DOJ AWPs, although in reality the information consisted simply of prices considered generally and currently paid in the marketplace.) The Transmittal instructed the carriers to consider those alternate wholesale prices in determining Medicare reimbursement amounts. (*Id.*)

DEFENDANTS' RESPONSE: Disputed that the DOJ AWPs "in reality . . . consisted simply of prices considered generally and currently paid in the marketplace" as the Government has offered no evidentiary support for that assertion and Defendants dispute the Government's characterization of the DOJ AWPs. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants do not dispute that CMS sent Transmittal AB-00-86 in September 2000, instructing Medicare carriers to consider the DOJ AWPs, or that the Program Transmittal contained alternate prices for 32 different drugs, including some of the subject drugs. Defendants further state that the Medicare carriers never used the DOJ AWPs and that over 89 members of Congress sent a letter to HCFA stating that they did not approve of the use of the DOJ AWPs, prompting HCFA to retract the Program Memorandum. Congress also later passed legislation prohibiting HCFA from using the DOJ AWPs. In addition, many States either refused to use the DOJ AWPs entirely, used only some of them, or discontinued use after a short duration. (*See* Roxane SOF ¶¶ 66-73.)

18. CMS did retract the September 2000 Program Memorandum. (Roxane Tab 121 (November 1 7, 2000 Program Memorandum to Carriers and Intermediaries)) However, it was not a rejection of the need for pricing information pricing information reflective of what was generally and currently paid in the marketplace. A subsequent HCFA program memorandum made clear that the purpose was to give the General Accounting Office (GAO) time to review Medicare payment policies and to make specific recommendations to the Secretary and Congress as to how to revise drug payment methodologies. (Abbott Ex. BD (May 3, 2001 Program Memorandum from HCFA to Carriers and Intermediaries))

DEFENDANTS' RESPONSE: Disputed that CMS's retraction of the September 2000 Program Memorandum "was not a rejection of the need for pricing information reflective of what was generally and currently paid in the marketplace," as the Government has offered no evidentiary support for that assertion. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Undisputed that a subsequent program memorandum stated that one reason for the retraction was to give the GAO time to review Medicare payment policies; however, the Government omits the critical undisputed fact that many Congressional members objected to CMS's use of the DOJ AWPs and later passed legislation prohibiting HCFA from using the DOJ AWPs. (*See* Roxane SOF ¶¶ 66-73; response to ¶ 17, *supra*.)

19. Indeed, the Benefits Improvement and Protection Act of 2000 arose out of efforts by Congress to stop what one representative termed "illegal behavior" and an "outrage." (Henderson Common Exhibit 9 (Medicare Payments for Currently Covered Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means, 107th Cong. 7 (2002) (statement of Rep. Stark, Member, House Comm. on Ways and Means))

DEFENDANTS' RESPONSE: Defendants dispute that the legislative intent behind the Benefits Improvement and Protection Act of 2000 can be inferred from the comments cited by the Government. Defendants further dispute that this paragraph is material to any of the parties' motions for summary judgment. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party

contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005).

20. On September 21, 2001, the GAO issued the report as directed by Congress. The GAO report recommended:

> Establish Medicare payment levels for part-B prescription drugs and their delivery and administration that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers.

(Henderson Common Exhibit 39 (Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118, September 21, 2001))

DEFENDANTS' RESPONSE: Undisputed. The September 2001 GAO report also noted large spreads for ipratropium bromide and some of the other drugs at issue in this litigation. (*See* Roxane SOF ¶ 87.)

21. Medicaid is a federal-state program to assist the poor, elderly, and disabled in obtaining medical care. 42 C.F.R. § 430.0 (2009). Under the Medicaid Act, which is Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 - 1396v, the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by the U.S. Department of Health and Human Services ("HHS"). 42 U.S.C. §§ 1396; 42 C.F.R. §§ 430.0, 430.10 - 430.20 (2009). One requirement is that the state have a State Plan that includes a methodology for reimbursing health care providers. 42 U.S.C. §§ 1396a(a), 1396d(a). A declaration authenticating the state plans produced by the United States in this case is attached to the Henderson Common Declaration. (Henderson Common Exhibit 44 (Declaration of William S. Lasowski))

DEFENDANTS' RESPONSE: Admitted.

22. Federal regulations require that state Medicaid programs' payment for drugs not subject to Federal Upper Limits not exceed, in the aggregate, the estimated acquisition cost of the drug plus a reasonable dispensing fee established by the agency. 42 C.F.R. § 447.331. For purposes of this regulation, the term "estimated acquisition cost" was defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301.

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 22. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 22 could be read to state undisputed or material facts, they are disputed. States, not the federal government, set the rate at which they pay pharmacies for dispensing drugs to Medicaid recipients. The federal government helps states provide covered services, such as drugs, to Medicaid recipients. The federal government does not dictate the formula that states use to determine the amount they will pay pharmacies, or prescribe limits on the state payments to pharmacies. The federal regulations cited by the United States establish guidelines governing the federal government's financial assistance to the state Medicaid programs relating to their payments for drugs. (*See* Defs. Comb. Memo. at 4-6; Defs. Comb. SOF ¶¶ 15, 24-29.)

Further responding, the federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* Defs. Comb. Memo. at 4-6, 9-11; Defs. Comb. SOF ¶¶ 14-36; 42 U.S.C. § 1396a(a)(30)(A).)

23. State Medicaid programs required accurate, current and comprehensive pricing information in order to process many hundreds of thousands if not millions of

claims for reimbursement on many thousands of different products. (Henderson Common Exhibit 10 (9/23/2008 Hillblom Dep. (California)), at 94:22 - 95:18); Henderson Common Exhibit 11 (12/1 5/2008 Dubberly Dep. (Georgia)), at 61:5-62:16; Henderson Common Exhibit 12 (1 1/18/2008 Parker Dep. (Illinois)), at 62:5 - 64:9, 67:5 -68:16; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:7 - 346:18; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:13; Henderson Common Exhibit 15 (12/15/2008 Stevens Dep. (New Mexico)), at 312:4 -315:22; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 101:2 - 104:21; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep., (Vermont)), at 357:1 - 358:22; Henderson Common Exhibit 18 (12/4/2008 Hayashi Dep. (Virginia)), at 27:6 -29:11)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 23. Rather, what the United States provides in paragraph 23 is an argument; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 23 could be read to state undisputed or material facts, they are disputed to the extent that the United States suggests state Medicaid programs had to rely upon prices reported by the compendia for processing the claims at issue in these cases. States did not have to rely upon prices reported by the compendia to adjudicate claims for the drugs at issue. Many states either relied upon Federal Upper Limits, established MACs, or utilized other methods to set prices for the drugs at issue. The MAC prices set by the states usually had nothing to do with compendia prices; rather these prices relied upon prices gathered directly from wholesalers or pharmacy providers. (*See* Defs. Comb. SOF ¶¶ 79-82.) When states did utilize AWPs or WACs published by the compendia, they did so with full knowledge that those prices were not an accurate reflection of acquisition costs. (*See* Defs. Comb. Memo. at 8-11; Defs. Comb. SOF ¶¶ 43, 45, 59.)

24. State Medicaid programs relied on published AWPs (and in some cases wholesale acquisition cost (WAC), *see infra* ¶¶ 30, 34 and 36-84) to estimate acquisition costs and process claims for reimbursement. It would not have been possible for States to process Medicaid claims without relying on AWPs and WACs published by the compendia. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), at 43:16 - 44:21, 63:12 - 64:17; Henderson Common Exhibit 20

(12/9/2008 Fine Dep. (Maryland)), at 48:11 - 50:15; Henderson Common Exhibit 13 (12/3/2008 Cheloha Dep. (Nebraska)), at 341:12 - 345:11, 348: 12 - 350: 10; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 282:7 - 284:22; Henderson Common Exhibit 22 (10/29/2008 Clifford Dep. (New Hampshire)), at 203:9 - 203:12; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 70:3 -72:16; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 43:2 - 44:22; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep.(Vermont)), at 358:1 - 358:22; Henderson Common Exhibit 23 (11/24/08 Hautea-Wimpee Dep. (Washington)), at 137:1 - 138:21)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 24. Rather, what the United States provides in paragraph 24 is an argument; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 24 could be read to state undisputed or material facts, they are disputed to the extent that the United States suggests state Medicaid programs had to rely upon prices reported by the compendia for processing the claims at issue in these cases. States did not have to rely upon prices reported by the compendia to adjudicate claims for the drugs at issue. Many states either relied upon Federal Upper Limits, established MACs, or utilized other methods to set prices for the drugs at issue. The MAC prices set by the states usually had nothing to do with compendia prices; rather these prices relied upon prices gathered directly from wholesalers or pharmacy providers. (*See* Defs. Comb. SOF ¶¶ 79-82.) When states did utilize AWPs or WACs published by the compendia, they did so with full knowledge that those prices were not an accurate reflection of acquisition costs. (*See* Defs. Comb. Memo. at 8-11; Defs. Comb. SOF ¶¶ 43, 45, 59.)

25. The firm Myers and Stauffer LC has provided support to the United States' expert witness Mark G. Duggan, Ph.D. As part of that support, Myers and Stauffer gathered information concerning the methodologies used by the Medicaid programs of 48 States and the District of Columbia (the Covered States) to reimburse pharmacy providers for prescription drugs. (Henderson Common Exhibit 24 (Declaration of Kristopher Knerr (Knerr Decl.) ¶¶ 4-12). The information gathered by Myers and Stauffer was described in a series of summaries that drug payment methodologies for each state in the damages reports

(Covered States). The summaries and all supporting information were produced to the defendants in connection with the United States' expert disclosures.

DEFENDANTS' RESPONSE: Admitted, with qualification. Myers & Stauffer also prepared a summary of the drug payment methodology for Ohio; that summary did not accurately summarize Ohio's payment methodology. The United States has provided Defendants with multiple versions of the summaries prepared by Myers & Stauffer, some of which were produced after the United States' expert disclosures.

However, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

26. Subsequent to those disclosures, Myers and Stauffer has updated the methodology summaries to reflect information obtained in discovery. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 13-14) All additional materials relied upon by Myers and Stauffer in connection with the updating of the methodology summaries were produced to the defendants on July 24, 2009. (*Id.*, ¶ 13)

DEFENDANTS' RESPONSE: Admitted, with qualification. Defendants do not believe all of the changes and additions to the Myers & Stauffer summaries "reflect information obtained in discovery." Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

27. In preparing the summaries, Myers and Stauffer relied upon (a) State Plan Amendments obtained from CMS through DOJ; (b) deposition testimony (including testimony from state officials regarding the actual implementation of the payment methodology), deposition exhibits, and documents produced by

Covered States pursuant to subpoenas; (c) state statutes, regulations and declarations; (d) annual publications of the National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, from 1990 through 2005/2006; (e) communications with officials of State Medicaid agencies; and (f) policy manuals, provider bulletins, and other similar materials available on state Medicaid agency websites. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 8-10 and 12-13)

DEFENDANTS' RESPONSE: Because Defendants did not work with Myers & Stauffer during their research and preparation of the State methodology summaries, Defendants cannot attest to what information Myers & Stauffer relied upon in preparing their summaries. The Knerr Declaration speaks for itself. Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

28. The methodology summaries are Attachment 1 to Knerr Decl. The information in each summary accurately summarizes the underlying data that was gathered by Myers and Stauffer. (Henderson Common Exhibit 24, (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Because Defendants did not work with Myers & Stauffer during their research and preparation of the State methodology summaries, Defendants cannot attest to whether the State methodology summaries accurately summarize all of the underlying data that was gathered by Myers & Stauffer. Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule. (*See also* response to ¶ 35, *infra*.)

29. Currently all Covered States except for Indiana reimburse pharmacy providers for prescription drugs under a "lower of' methodology in which payment is made based, at least in part, on the lower of(a) the State's estimated acquisition cost (EAC) plus a dispensing fee, (b) the pharmacy's usual and customary charge (U&C) (sometimes referred to as the "billed amount"), or (c) the Federal Upper Limit (FUL) established by CMS pursuant to 42 C.F.R. § 447.332; (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 18) Indiana recently eliminated the FUL from its methodology. *(Id.)*

DEFENDANTS' RESPONSE: Defendants dispute the accuracy and materiality of the above statement. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). Most states currently include a State Maximum Allowable Cost (state MAC) into their payment formula, and many states utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans. (*See* response to ¶ 31, *infra*; *see also* Roxane SOF ¶¶ 269-79.) Also, not all of the Covered States currently have a stated methodology that would pay the lower of EAC, U&C, or FUL (*e.g.*, Arkansas). Moreover, the methodologies "currently" used by the states are subject to change. Because the methodologies "currently" utilized by the states are not what is principally at issue, the above statement is not material.

Further responding, the state plan and other material reviewed by Myers & Stauffer do not confirm how the states operated their payment systems in practice. Nor are the state plans and other material reviewed by Myers & Stauffer competent evidence of what the states allegedly "would have paid" on the claims at issue had Defendants reported lower prices for the drugs at issue. Inserting the "corrected" AWPs, WACs, and Direct Prices calculated by Plaintiffs' expert into existing payment methodologies would also lead to anomalous payment amounts, such as when states applied large discounts off of AWP. Also, Plaintiffs' theory that

the states would have utilized lower prices with their existing payment methodologies – with no changes to their drug payment methodologies – is speculative and inconsistent with the record evidence. For example, extensive record evidence shows that states permitted a margin on ingredient payments in order to promote the use of generic drugs, subsidize inadequate dispensing fees, and achieve other policy objectives. (*See* Defs. Comb. SOF ¶¶ 38, 41, 43, 45.)

Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

30. For the period 1991 to the present, each Covered State used AWP as the primary basis for determining the EAC component of their drug payment methodology, during at least part of that period; 42 of the Covered States used AWP as the primary basis for determining the EAC component of their State's drug payment methodology for the entire time period of 1991 to present. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24a). The remaining Covered States used WAC or a combination of AWP and WAC as the basis for determining the EAC component of their state's drug payment methodology. (*Id.*, ¶ 24b)

DEFENDANTS' RESPONSE: Disputed. Plaintiffs' Complaints contend that "AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer who then administers it to a patient" and that "WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail customer." The record evidence – including the state plan material, depositions, and other information relied upon by Myers & Stauffer – shows that the states explicitly defined and/or understood that the terms "AWP," "WAC," and "Direct Price" referred to prices published in the compendia (such as First DataBank) that the states knew generally did not approximate acquisition cost for generic drugs. (*See* Defs. Comb. SOF ¶¶ 37, 43, 45, 59.) Because paragraph

30 may be intended to use the terms AWP and WAC in ways inconsistent with the record evidence, it is disputed.

Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

31. During the period 1991 to the present, only six Covered States have deviated from the methodology described in the paragraph 29, above: (1) Delaware used Actual Acquisition Cost before May 1 , 1997; (2) Michigan used Actual Acquisition Cost, with a limit based on AWP, before September 15, 1995; and (3) Alaska, New York, Arkansas and Massachusetts, each for specific periods of time, did not include EAC in the "lower of' algorithms when the drug was subject to a FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 19)

DEFENDANTS' RESPONSE: Disputed. Paragraph 29 suggests that, from 1991 to the present, all drug claims were, in fact, paid on the lower of (a) the State's estimated acquisition cost (EAC) plus a dispensing fee, (b) the pharmacy's usual and customary charge (U&C), or (c) the Federal Upper Limit established by CMS. Most states included a State Maximum Allowable Cost (state MAC) into their payment formula, and many states utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans. (*See* Roxane SOF ¶¶ 269-79.) For example, Georgia's 30(b)(6) witness testified that compounded drugs were reimbursed at undiscounted average wholesale price "because compounding takes a pharmacist to actually mix the medications, calculate the -- calculate the individual components, weigh the components out, often doing a process called 'geometric dilution' with topical products. It's much more involved than – than any of the other dispensing actions, including simple admixtures." (Reid Common Decl., Ex. 7, at 336-37.) Also, many states appeared to price intravenous or compounded drug prescriptions differently than the

normal methodologies reflected in the state plans. (*See, e.g.*, Reid Common Decl., Ex. 3, at 162-67, 310-12; Reid Common Decl., Ex. 4, at 286-87; Dkt. No. 6189 ¶¶ 21, 22.)

In addition, Hawaii did not always follow its state plan. After 2001, in instances where there was a FUL for a drug that was higher than the state MAC, it was Hawaii's practice to reimburse at the higher FUL. This is contrary to Hawaii's State Plan, which provided for reimbursement at "the lower of" billed charges, the provider's usual and customary charge, estimated acquisition cost, FUL or the State MAC. (*See* Reid Decl., Ex. 209, at 174:4-188:14; Reid Decl., Ex. 210, at 4(a)2.)

Further responding, the state plan and other material reviewed by Myers & Stauffer do not confirm how the states operated their payment systems in practice.

Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

32. During the period 1991 to the present, 42 of the Covered States have implemented a State Maximum Allowable Cost (SMAC) (sometime under different names) feature. A SMAC is an upper limit established by the State, similar to the FUL, but often determined based on criteria different than the FUL. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 20, 24f) Twenty two of these Covered States have implemented a SMAC program during the entire time period. *(Id*., ¶ 240 In all of these Covered States, the SMAC program is incorporated into the "lower of' methodology described above, except that Hawaii does not apply the SMAC if an FUL is in place. *(Id*., ¶¶ 20, 24e-f)

DEFENDANTS' RESPONSE: Admitted, with the exception of last sentence. To the extent that the last sentence asserts that, from 1991 to the present, the stated methodologies for each of the Covered States provided that these would pay the lower of EAC, U&C, FUL, or SMAC, it is disputed. In addition to the deviations described in paragraph 31, *supra*, many states

utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans. (*See* response to ¶ 31, *supra*; *see also* Roxane SOF ¶¶ 269-79.)

Further responding, the state plan material relied upon by Myers & Stauffer indicates instances where states would not pay the lower of EAC, U&C, FUL, or SMAC, including Arkansas, Massachusetts, Georgia, and Washington.

Further responding, the state plan and other material reviewed by Myers & Stauffer do not confirm how the states operated their payment systems in practice.

Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule..

33. Twenty-five Covered States add to their "lower of' algorithm, for at least some of the time period, the wholesale pricing information provided in 2000 by the Department of Justice and the National Association of Medicaid Fraud Control Units and published by First DataBank. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 21)

DEFENDANTS' RESPONSE: Disputed. The basis cited for this statement (Knerr Decl. ¶ 21) is not consistent with the statement. The Knerr Declaration indicates that "Twenty-nine (29) states have also used the 'DOJ Price' plus a dispensing fee as part of their reimbursement methodology." (Henderson Common Decl., Ex. 24 ¶ 21.)

Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

34. Forty-three Covered States use First DataBank or First DataBank together with Medispan or Red Book as their primary source of information for determining EAC. Of the remaining six Covered States, five use MediSpan as their primary source for determining EAC, and one State uses Red Book for determining EAC. Some Covered States have changed the compendia they use for their prescription pricing, as noted in the respective Myers and Stauffer summaries. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 24c)

DEFENDANTS' RESPONSE: Defendants dispute the materiality of the above statement because it provides the purported source of information that states use to determine EAC currently, not during the relevant time period. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). It is relevant, however, that despite extensive evidence that prices reported by the compendia do not reflect acquisition cost for generic drugs, states continue to use those prices in their payment methodologies.

Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

35. The following paragraphs 36 through 85, concerning the accuracy of State methodology summaries, refer to the summaries in Attachment 1 to the Knerr Decl. The "supporting materials" means the supporting materials referenced in ¶¶ 5 and 12-13 of the Knerr Declaration.

DEFENDANTS' RESPONSE: The United States does not state material or undisputed facts in paragraph 35. Therefore, no response should be required. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of

record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005); *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006).

With respect to the "State methodology summaries" prepared by the accounting firm of Myers & Stauffer referenced in paragraphs 36-84, *infra*, Defendants respond as follows: Defendants dispute that the State methodology summaries represent, as the United States contends in paragraphs 36-84, "true and accurate summar[ies] of the features of the prescription drug payment methodolog[ies]" of the states.

The State methodology summaries omit information necessary to be "true and accurate" summaries of the states prescription drug payment methodologies. While the summaries indicate whether the states used "AWP," "WAC," or "Direct Price," and at times indicate where the state obtained that information (usually First DataBank), they fail to describe how the states defined or understood those terms. The record evidence – including the state plan material, depositions, and other information relied upon by Myers & Stauffer – shows that the states explicitly defined and/or understood that the terms "AWP," "WAC," and "Direct Price" referred to prices published in the compendia (such as First DataBank) that the states generally knew did not approximate acquisition cost for generic drugs. (*See* Defs. Comb. SOF ¶¶ 37, 43, 45, 59.) Because the State methodology summaries fail to provide that information, or describe how states arrived at the EAC levels contained in their state plans, they are not true and accurate summaries of the prescription drug payment methodologies of the states.

Further responding, the State methodology summaries are not competent evidence of how states paid for the drug clams at issue; the summaries contain no information on how the claims

at issue were actually paid. Many of the claims at issue were reimbursed on the basis of a FUL, MAC, U&C charge, or other basis for reimbursement, yet the summaries provide no information regarding whether, or when, the states applied FULs, MACs, or other bases for reimbursement for the claims at issue. (*See* Roxane SOF ¶¶ 269-79.) Nor do the summaries explain how states arrived at the pricing levels and payment methodologies used for the drug claims at issue.

Further responding, during the course of its work and discovery, Myers & Stauffer has learned of numerous instances where states did not actually operate their payment systems consistent with their state plans (*see, e.g.*, Henderson Common Decl., Ex. 24, at ¶ 24(e)), or had alternative payment bases not described in the state plans (*e.g.*, for intravenous or compounded prescriptions). (*See* Roxane SOF ¶¶ 269-79.) As a result, Myers & Stauffer has had to update the summaries to account for additional information.

Further responding, the State methodology summaries are not competent evidence of what the states allegedly "would have paid" on the claims at issue had Defendants' reported lower prices for the drugs at issue. While the summaries describe a "lower-of" methodology, the summaries do not confirm that this was how the states operated their payment systems in practice. Moreover, inserting the "corrected" AWPs, WACs, and Direct Prices calculated by Plaintiffs' expert into existing payment methodologies would also lead to anomalous payment amounts, such as when states applied large discounts off of AWP. Also, Plaintiffs' theory that the states would have utilized lower prices into their existing payment methodologies – with no changes to their drug payment methodologies – is speculative and inconsistent with the record evidence. For example, extensive record evidence shows that states permitted a margin on ingredient payments in order to promote the use of generic drugs, subsidize inadequate dispensing fees, and achieve other policy objectives. (*See* Defs. Comb. SOF ¶¶ 38, 41, 43, 45.)

Because these facts are not reflected in the Myers & Stauffer State methodology summaries, the summaries are not true and accurate summaries of the features of the prescription drug payment methodologies of the states.

Further responding, the State methodology summaries are also vague in numerous instances. For example, the summary for Iowa states:

> Effective 10/1/2003 with NCPDP version 5.1 implementation, all compounds had to be billed on an ingredient by ingredient basis. Prior to 5.1, Iowa Medicaid allowed pharmacies to bill for compounded claims using the NDC of one of the active ingredients, adjusting the price to the full compound price online for those claims $30 and under. Claims that exceeded $30 had to be billed on the Universal Claim Form on an ingredient by ingredient basis.

While this language strongly suggests that compounded drug claims in the state of Iowa were subject to a floor of $30, the impact of this provision on the drug claims at issue is not explained.

Further responding, the summaries prepared for states which did not always include AWP in their EAC methodologies, such as Florida, Alabama and Rhode Island, do not address whether those states utilized an "AWP proxy" for WAC.

Finally, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

36. The summary for the State of Alabama is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

37. The summary for the State of Alaska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

38. The summary for the State of Arkansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

39. The summary for the State of California is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

40. The summary for the State of Colorado is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

41. The summary for the State of Connecticut is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

42. The summary for the State of Delaware is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

43. The summary for the State of Florida is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

44. The summary for the State of Georgia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

45. The summary for the State of Hawaii is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

46. The summary for the State of Idaho is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

47. The summary for the State of Illinois is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

48. The summary for the State of Indiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

49. The summary for the State of Iowa is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

50. The summary for the State of Kansas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the

supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

51. The summary for the Commonwealth of Kentucky is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

52. The summary for the State of Louisiana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

53. The summary for the State of Maine is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

54. The summary for the State of Maryland is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

55. The summary for the Commonwealth of Massachusetts is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

56. The summary for the State of Michigan is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

57. The summary for the State of Minnesota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

58. The summary for the State of Mississippi is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

59. The summary for the State of Missouri is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

60. The summary for the State of Montana is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

61. The summary for the State of Nebraska is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

62. The summary for the State of Nevada is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

63. The summary for the State of New Hampshire is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

64. The summary for the State of New Jersey is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

65. The summary for the State of New Mexico is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

66. The summary for the State of New York is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

67. The summary for the State of North Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

68. The summary for the State of North Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

69. The summary for the State of Oklahoma is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

70. The summary for the State of Oregon is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the

supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

71. The summary for the Commonwealth of Pennsylvania is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ *5)*

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

72. The summary for the State of Rhode Island is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

73. The summary for the State of South Carolina is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

74. The summary for the State of South Dakota is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

75. The summary for the State of Tennessee is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

76. The summary for the State of Texas is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

77. The summary for the State of Utah is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

78. The summary for the State of Vermont is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

79. The summary for the Commonwealth of Virginia is a true and accurate summary of features of the prescription drug payment methodology of that Commonwealth, as documented in the supporting materials for that Commonwealth. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

80. The summary for the State of Washington is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

81. The summary for the State of West Virginia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

82. The summary for the State of Wisconsin is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

83. The summary for the State of Wyoming is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

84. The summary for the District of Columbia is a true and accurate summary of features of the prescription drug payment methodology of that State, as documented in the supporting materials for that State. (Henderson Common Exhibit 24 (Knerr Decl.), ¶ 5)

DEFENDANTS' RESPONSE: Disputed. *See* response to ¶ 35, *supra*.

85. States request federal Medicaid funds on a quarterly basis. Henderson Common Exhibit 25 (Declaration of Kristin A. Fan (Fan Decl.), ¶ 5) The process generally begins 45 days before the upcoming quarter begins, with each state submitting to CMS a budget of what it projects the state will spend during the upcoming quarter. *Id.;* 42 C.F.R. § 430.30(b). The state Medicaid official provides the information electronically using a Form CMS-37. *(Id.*, ¶ 5) Along with the overall funding request, the state will provide estimates of various types service, including drug costs. *Id.* Further, the CMS-37 includes a certification that states in part:

> The fiscal year budget estimates only include expenditures under the Medicaid program under title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under title XXI of the Act, that are allowable in accordance with applicable implementing Federal, state, and local statutes, regulations, policies, and the state plan approved by the Secretary and in effect during the fiscal year under title XIX of the Act for the Medicaid program, and as applicable, under title XXI of the Act for the SCHIP. The budget estimates are based upon the most reliable information available to the state.

Id.

DEFENDANTS' RESPONSE: Disputed. Defendants dispute that states provide estimates of "drug costs," as this alleged fact is not supported by the Government's proffered evidence. Moreover, Defendants object to the Government's reliance on Fan's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Fan's Declaration. Further responding, Defendants state that Fan's Declaration is hearsay and violates the Best Evidence Rule.

86. A state's budget estimate for a given quarter is normally based on the state's Medicaid expenditures in prior quarters. (Henderson Common Exhibit 25 (Fan

> Decl.), ¶ 6) Therefore, if drug expenditures in prior quarters are improperly inflated, this would likely cause, absent an adjustment, the budget estimate for a subsequent quarter to be inflated. *Id.*

DEFENDANTS' RESPONSE: Admitted, with qualification. The Form CMS-37 includes a field for "Prescribed Drugs," but does not break down a state's budget estimate into drug ingredient costs or dispensing fees. Nor does the Form CMS-37 break down a state's budget estimate for individual drugs. The federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* Defs. Comb. Memo. at 4-6, 9-11; Defs. Comb. SOF ¶¶ 14-36; 42 U.S.C. § 1396a(a)(30)(A).)

Further responding, the United States has provided no evidence that any state's budget estimates for any quarter were "improperly inflated" or in any way inconsistent with the federal, state, and local statutes, regulations, policies, and the state plans approved by HHS. Moreover, Defendants object to the Government's reliance on Fan's Declaration, which was submitted after the close of discovery, to the extent it contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Fan's Declaration. Further responding, Defendants state that Fan's Declaration is hearsay and violates the Best Evidence Rule.

87. The CMS 37 form is sent to the appropriate regional CMS office. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 7); 42 C.F.R. § 430.30(b), (d). Upon receipt, regional office staff will review the form and make recommendations to the CMS central office as to whether the state funding request should be approved, approved with adjustments, or denied. 42 C.F.R. § 430.30(d); *Id.*, ¶ 7) The CMS central office reviews the regional analyst's recommendations. *(Id.*, ¶ 7) In deciding what funding level to approve for the following quarter, the CMS central office "considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant." *(Id.;* 42 C.F.R. § 430.30(d)(2)) In determining whether any adjustments should be made under subsection (d)(2) of the regulation, the central office examines any expenditures from previous quarters. *(Id*., ¶ 7; 42 C.F.R. § 430.30(d)(2)) Once the funding request is approved, the state can draw down the federal monies on a federal letter of credit for the allotted amount as costs are incurred. *(Id*., ¶ 7) The State draws down federal funds through a commercial bank and the Federal Reserve System. *Id.*

DEFENDANTS' RESPONSE: Admitted.

88. Section 430.30(d)(3), 42 C.F.R., provides that the grant award "authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements." (Emphasis added). It is CMS's position that the state's quarterly federal Medicaid award is only to be used to reimburse Medicaid providers for actual payments. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 8) In practice, a state draws down federal funds as actual payments are made by the State to Medicaid providers, including pharmacies and physicians seeking payment for drugs. *Id.* Thus, if a state overpays providers because of false provider claims, the state's draw-down on the letter of credit for the federal share will be affected, unless an adjustment is made. *(Id*., ¶ 8)

DEFENDANTS' RESPONSE: Admitted, with qualification. The United States has provided no evidence that any state "overpa[id] providers because of false provider claims" attributable to the drugs at issue, or that any federal grant payments were made that were in any way inconsistent with the federal, state, and local statutes, regulations, policies, and the state plans approved by HHS. The federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual

drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* Defs. Comb. Memo. at 4-6, 9-11; Defs. Comb. SOF ¶¶ 14-36; 42 U.S.C. § 1396a(a)(30)(A).) Moreover, Defendants object to the Government's reliance on Fan's Declaration, which was submitted after the close of discovery, to the extent it contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Fan's Declaration. Further responding, Defendants state that Fan's Declaration is hearsay and violates the Best Evidence Rule.

89. After each calendar quarter, the state must submit to CMS a reconciliation of its actual Medicaid expenditures against the monetary advance made on the basis of the Form 37. 42 C.F.R. § 430.30(c). The state electronically submits this information using a Form CMS-64. A State submitting the Form CMS 64 makes a certification that includes the following:

> I certify that:
>
> 1. I am the executive officer of the state agency or his/her designate authorized by the state to submit this form.
>
> 2. This report only includes expenditures under the Medicaid program under Title XIX of the Social Security Act (the Act), and as applicable, under the State Children's Health Insurance Program (SCHIP) under Title XIX of the Quarter Ended indicated above under Title XXI of the Act.
>
> 3. The expenditures included in this report are based on the state's accounting of actual recorded expenditures, and are not based on estimates.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 9)

DEFENDANTS' RESPONSE: Admitted.

90. The CMS web site provides an explanation of the Form CMS-64. Centers for Medicare and Medicaid Services, Medicaid Budget and Expenditure System

(Medicaid Quarterly Expense Report), available at http://www.cms.hhs.gov/MedicaidBudgetExpendSystem!02CMS64.asp. It states in part:

> The amounts reported on Form CMS-64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed. Form CMS-64 is a statement of expenditures for which states are entitled to Federal reimbursement under Title XIX and which reconciles the monetary advance made on the basis of Form CMS-37 filed previously for the same quarter. Consequently, the amount claimed on the Form CMS-64 is a summary of expenditures derived from source documents such as invoices, cost reports and eligibility records.

(Henderson Common Exhibit 25 (Fan Decl.), ¶ 10)

DEFENDANTS' RESPONSE: Admitted.

91. The information in the Form CMS-64 is a source of information used in adjusting future Form-37 funding requests. (Henderson Common Exhibit 25 (Fan Decl.), ¶ 11; 42 C.F.R. § 430.30(d)(2)) If CMS believes that it has overpaid a state based on its review of the Form-64, or otherwise, CMS may adjust future authorizations to offset the overpayment or seek to recover the amount overpaid. (42. U.S.C. § 1396b(d)(5); *Id.*, ¶ 11) While federal funding is made available prospectively to state Medicaid programs, the quarterly funding level for a state's Medicaid program is directly determined based on the state's actual, quarterly Medicaid expenditures. *(Id.*, ¶ 11)

DEFENDANTS' RESPONSE: Admitted, with qualification. The Form CMS-64 includes a field for "Prescribed Drugs," but does not break down a state's expenditures into drug ingredient costs or dispensing fees. Nor does the Form CMS-64 break down a state's expenditures for individual drugs. The federal regulations measure a state's expenditures for drug ingredient costs and dispensing fees "in the aggregate," and were designed to provide states with significant flexibility in the design and operation of their prescription drug programs. State Medicaid programs were permitted to pay more than estimated acquisition cost for individual drugs, were permitted to pay more than estimated acquisition cost in order to offset lower than reasonable dispensing fees, and were statutorily required to set rates for the dispensing of

prescription drugs "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* Defs. Comb. Memo. at 4-6, 9-11; Defs. Comb. SOF ¶¶ 14-36; 42 U.S.C. § 1396a(a)(30)(A).) Moreover, Defendants object to the Government's reliance on Fan's Declaration, which was submitted after the close of discovery, to the extent it contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Fan's Declaration. Further responding, Defendants state that Fan's Declaration is hearsay and violates the Best Evidence Rule.

Further responding, the United States has provided no evidence that any state's expenditures for any quarter were inconsistent with the federal, state, and local statutes, regulations, policies, and the state plans approved by HHS.

92. Many third-party payors, including state, federal government and private health plans, use database products from national drug pricing compendia in determining their payment levels for drugs eligible for payment under their benefit plans. (Henderson Common Exhibit 24 (Knerr Decl.), ¶¶ 25-84); *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp.2d 172, 178 (D. Mass. 2003)) In the separate statements of undisputed facts as to each defendant the plaintiffs list the AWPs reported by FDB for each defendant's Subject Drugs. In all cases in which a Defendant has produced records showing the amounts it reported to FDB as either its AWPs or other reported prices *(e.g.* , list price or WAC) used to determine the AWP by application of a fixed markup.

DEFENDANTS' RESPONSE: Disputed. Defendants dispute the Government's alleged fact, "In all cases in which a Defendant has produced records showing the amounts it reported to FDB as either its AWPs or other reported prices (e.g., list price or WAC) used to determine the AWP by application of a fixed markup," because it is incomprehensible and on the grounds that it is unsupported by citations to the record, as is required by Local Rule 56.1. *See* O'Brien v. Town of Agawam, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants also dispute the alleged fact that "Many third-party payors, including state, federal government and private health

plans, use database products from national drug pricing compendia in determining their payment levels for drugs eligible for payment under their benefit plans" as it is not supported by the Government's proffered evidence. Defendants also state that although the information provided by the pricing compendia may have been a part of the payment formulas used by some third-party payors, it was universally understood that the published prices did not represent actual acquisition costs paid by providers. (*See* Defs. Comb. Memo. at 8-11.) The documents and data produced by Defendants and by the pricing compendia are the best evidence of their content. Defendants further state that Dey's AWPs were set at a percentage discount to the therapeutically equivalent brand AWP pursuant to industry practice and instruction from First Databank, and that Dey's WACs were initially set at a discount to its AWPs. Dey's WACs were its invoice prices to wholesalers, were regularly updated, and declined over time as prices for Dey's drugs decreased. (*See* Dey SOF ¶¶ 66-77.) Moreover, Defendants object to the Government's reliance on Knerr's Declaration, which was submitted after the close of discovery, because it contradicts pre-existing facts in the record, and because Defendants have not yet had the opportunity to conduct discovery with respect to Knerr's Declaration. Further responding, Defendants state that the Knerr Declaration is hearsay and violates the Best Evidence Rule.

93. **REDACTED**

DEFENDANTS' RESPONSE: **REDACTED**

94. **REDACTED**

DEFENDANTS' RESPONSE: REDACTED

95. On October 3, 2002, the Office of Inspector General for the Department of Health and Human Services published "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 67 Fed. Reg. 62057-62067 (Oct. 3, 2002). The Draft Guidance identified "major risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . " 67 Fed. Reg. at 62060. The Draft Guidance further stated:

> Many Federal and state health care programs establish reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act, if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately.
>
> 67 Fed. Reg. at 62060.

DEFENDANTS' RESPONSE: Undisputed that the OIG issued the cited draft guidance in the Federal Register in October 2002 and that the Federal Register contains the excerpted language. However, Defendants object as the above language is incomplete. The draft guidelines explicitly disclaimed that: (1) "The contents of this guidance should not be viewed as mandatory . . . . The document is intended to present voluntary guidance to the industry and not represent binding standards for pharmaceutical manufacturers," (67 Fed. Reg. 62058 (Oct. 3, 2002)), and (2) "This guide is not a compliance program" (*id*). Because the draft guidelines did not impose any binding obligations on Defendants, this passage is immaterial to any party's motion for summary judgment. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). Dey also disputes paragraph 95 for the reasons stated in Dey Resp. to US-Dey-SOF ¶ 177.

96. On May 5, 2003, the Office of Inspector General for the Department of Health and Human Services published final "OIG Compliance Program Guidance for Pharmaceutical Manufacturers." 68 Fed. Reg. 23731-23743 (May 5, 2003). The

Guidance identified "major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and Federal governments to establish payment . . . ." 68 Fed. Reg. at 23732. The Guidance identified "Specific Risk Areas" for pharmaceutical manufacturers, including "[i]ntegrity of data used by state and Federal governments to establish payment amounts." 68 Fed. Reg. at 23733. The Guidance further stated:

> Many Federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately."
>
> *Id.*

DEFENDANTS' RESPONSE: Undisputed that the OIG issued the cited guidance in the Federal Register in May 2003 and that the Federal Register contains the excerpted language. However, Defendants object as the above language is incomplete. The guidelines explicitly disclaimed that: (1) "This guide is not a compliance program." (68 Fed. Reg. 23731 (May 5, 2003)), and (2) "This guidance does not create any new law or legal obligations, and the discussions that follow are not intended to present detailed or comprehensive summaries of lawful and unlawful activity" (*id*. at 23733). Because these guidelines did not impose any binding obligations on Defendants, this passage is immaterial to any party's motion for summary judgment. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart,*

Kolasch & Birch, LLP, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005). Dey also disputes paragraph 96 for the reasons stated in Dey Resp. to US-Dey-SOF ¶ 177.

97. Pursuant to the Medicaid Drug Rebate Statute (Rebate Statute), pharmaceutical manufacturers (including Abbott, Dey and Roxane) are required to enter into a national Medicaid Rebate Agreement with the CMS. 42 U.S.C. § 1396r-8(a)(1). Once a manufacturer enters a rebate agreement with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. 42 U.S.C. § l396r-8(d).

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 97. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 97 could be read to state undisputed or material facts, they are disputed. 42 U.S.C. § 1396r-8(a)(1) does not require all pharmaceutical manufacturers to enter into a Medicaid Rebate Agreement, but rather requires a pharmaceutical manufacturer to enter into a Medicaid Rebate Agreement as a precondition to that manufacturer's drugs being reimbursed by state Medicaid programs. 42 U.S.C. § 1396r-8(d) permits state Medicaid programs to place further restrictions on drug coverage, such as formularies, prior authorization programs, and quantity restrictions. Dey also disputes paragraph 97 for the reasons stated in Dey Resp. to US-Dey-SOF ¶ 7 and Dey SOF ¶¶ 85-88.

98. Pursuant to the Rebate Statute, drug manufacturers (including Abbott, Dey and Roxane) are required to calculate and submit AMPs to CMS on at least a quarterly basis. 42 U.S.C. § l396r-8(b)(3) and (k)(1).

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 98. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 98 could be read to state undisputed or material facts, they are not disputed.

99. CMS administers the Rebate Statute in part by using a manufacturer's AMP information and drug utilization information submitted by States to calculate a "Unit Rebate Amount" (URA). 42 U.S.C. § 1396r-8(b)(2)(A). The URA is the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due. Reid Decl., Exhibit 34 at p. 5.

DEFENDANTS' RESPONSE: Disputed. The Unit Rebate Amount ("URA") is calculated solely from information provided by manufacturers. For instance, for non-innovator multiple-source drugs, the URA is 11 percent of the average manufacturer price ("AMP") as reported by the manufacturer. (*See* 42 U.S.C. § 1396r-8(b)(3); Reid Decl., Ex. 34, at p. 3, Enclosure A at ¶¶ I(a) and (dd).) CMS does not rely on any information submitted by states to calculate URAs. Dey also disputes paragraph 99 for the reasons stated in Dey SOF ¶¶ 89-90.

100. The Rebate Statute requires that AMPs provided to CMS be kept confidential and not be disclosed by CMS except for the purpose of carrying out the purposes of the rebate program. 42 U.S.C. § l396r-8(b)(3)(D).

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 100. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 100 could be read to state undisputed or material facts, they are disputed. 42 U.S.C. § 1396r-8(b)(3)(D) does not contain an unconditional requirement that CMS keep AMPs confidential. Nor does it unconditionally limit the use of AMPs to the Medicaid rebate program. During most of the time period relevant to this action, 42 U.S.C. § 1396r-8(b)(3)(D) provided in relevant part:

> Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph … is confidential and shall not be disclosed by the Secretary … or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except – (i) as the Secretary determines to be necessary to carry out this section …,

> (ii) to permit the Comptroller General to review the information provided, and
> (iii) to permit the Director of the Congressional Budget Office to review the information provided.

(Reid Common Decl., Ex. 11.) There is nothing contained in the text of this subsection that would prohibit CMS from using AMPs internally for purposes other than the Medicaid rebate program, or from publicly disclosing AMPs, or information derived from AMPs, in a manner that does not identify a particular manufacturer or wholesaler, or prices paid by a particular manufacturer or wholesaler. The section contemplates providing AMPs directly to state Medicaid agencies, as the text of the section expressly extends the disclosure limitations to state agencies and their contractors. Indeed, while CMS refused to provide AMPs to state agencies, CMS has informed states since at least 1997 that they were free to gather AMP information directly from manufacturers for their own uses. (*See* Reid Common Decl., Ex. 8.) Texas, California, Maine, and Vermont all require drug manufacturers to report AMPs directly to their respective Medicaid programs. (*See* 1 Tex. Admin. Code § 354.1927; Me. Rev. Stat. Ann. Tit. 22 § 2698-B; Vt. Stat. Ann. Tit. 33 § 2010(a); Reid Common Decl., Ex. 9.) Dey also disputes paragraph 100 for the reasons stated in Dey SOF ¶¶ 91-92 and 97-103.

101. The specific rebate agreements entered into between CMS and the defendants state as follows:

> Pursuant to Section l927(b)(3)(D) of the [Social Security] Act and this Agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices changed by the Manufacturer, except as necessary by the Secretary to carry out provisions of [the Rebate Statute].

(Roxane SOF, Tab 143, p. 9; Reid Decl., Ex. 34)

DEFENDANTS' RESPONSE: Admitted.

102. In a 1995 proposed rulemaking published at 60 Fed. Reg. 48442 (1995), the Department of Health and Human Services stated as follows concerning AMP information:

> C. Confidentiality of Manufacturer Price Information
>
> Comment: Many of the commenters believed that States should not have access to manufacturers' price information, including unit rebate amounts, since HCFA has access to this information. The commenters stated that the risk of disclosure and use of information for other purposes is too great.
>
> Response: We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by "the Secretary or a State agency (or contractor therewith)." By including States within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute. The unit rebate amount, which provides the rebate due per tablet, etc., and which is the end result of the manufacturer's calculation, is, in our opinion, the minimum amount of information States need to accomplish this. At the same time, the statute protects the manufacturer's pricing data from disclosure. In accordance with section 1927(b)(3)(D) of the Act, information disclosed by manufacturers in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act, *5* U.S.C. *552)* must not be disclosed by HCFA, the State agency, or its contractors in a form that reveals the manufacturer, except as necessary for the Secretary of HHS to carry out the provisions of section 1927 and for the Comptroller General or the Director of the Congressional Budget Office to review the information provided.

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 102 accurately quotes 60 Fed. Reg. 48442 (1995). Defendants dispute that the quoted portions of 60 Fed. Reg. 48442 (1995) constitute a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their response to paragraph 100 above. Defendants further state that, in a 2001 report, the OIG discussed the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and CMS's interpretation of them:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average

> manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(*See* Reid Decl., Ex. 38, at 22.) Ann Maxwell, the Government's 30(b)(6) designee and a regional inspector general at the OIG, testified that this paragraph "accurately discusses the confidentiality provisions surrounding AMP." (Reid Decl., Ex. 39, at 129:1-131:3.) Dey also disputes paragraph 102 for the reasons stated in Dey SOF ¶¶ 91-92 and 97-103.

103. In an exchanged of letters in October 1991 and May 1992 relating to the State of Hawaii's implementation of the Medicaid Rebate statute, HCFA requested, and Hawaii gave assurances that "the State will keep the unit rebate amount confidential and will not disclose it for purposes other than rebate invoicing and verification." (Henderson Common Exhibits 27 and 28)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 103 accurately characterizes Henderson Common Exhibits 27 and 28. Defendants dispute that the quoted portion of Henderson Common Exhibit 28 is based upon a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100 and 102 above.

104. On or about April 22, 2004, CMS approved a New Hampshire State Plan Amendment allowing the State to enter into the Michigan Multi-State Pooling Supplemental Drug Rebate Agreement. The SPA included the statement, "[t]he unit rebate amount is confidential and cannot be disclosed in accordance with

Section l927(b)(3)(D) of the Social Security Act." (Henderson Common Exhibit 29; Dey Exhibit 95)

DEFENDANTS' RESPONSE: Defendants do not dispute that CMS approved the New Hampshire State Plan Amendment as described in paragraph 104 and do not dispute Henderson Common Exhibit 29 contains the language quoted in paragraph 104. Defendants dispute that the quoted language or the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) would prohibit CMS or New Hampshire from disclosing URAs or information derived from URAs in a manner that did not identify a specific manufacturer or wholesaler or prices paid by a specific manufacturer or wholesaler, or would otherwise prohibit CMS or New Hampshire from using URAs internally for purposes other the Medicaid rebate program. Defendants incorporate herein their responses to paragraphs 100 and 102 above.

105. A copy of the Michigan Multi-State Pooling Supplemental Drug Rebate Agreement signed by Dey (and which Dey marked "HIGHLY CONFIDENTIAL") states, "The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1 927(b)(3)(D) of the Social Security Act." Paragraph 7.3 of the Agreement states, "The parties further agree that any information provided to the state by the manufacturer pursuant to this agreement and this agreement itself constitute trade secrets and other confidential or proprietary commercial and financial information not subject to public disclosure." The Agreement includes a "Schedule 3" which states that the Supplemental Rebate Amount is calculated based in part on the "CMS Unit Rebate Amount " (Henderson Common Exhibit 30, Dey Exhibit 96)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 105 accurately describes Henderson Common Exhibit 30. Defendants dispute that the quoted language or the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) would prohibit CMS or any signatory to the Michigan Multi-State Pooling Supplemental Drug Rebate Agreement (the "Agreement") from disclosing URAs or information derived from URAs in a manner that did not identify a specific manufacturer or wholesaler or prices paid by a specific manufacturer or wholesaler, or would otherwise prohibit CMS or any signatory to the Agreement from using

URAs internally for purposes other the Medicaid rebate program. Defendants incorporate herein their responses to paragraphs 100 and 102 above.

106. In a September 2001 "Medicaid Drug Rebate Operational Training Guide" prepared by CMS's Center for Medicaid and State Operations, the agency stated that AMPs:

> are generally subject to both privacy and trade secret restrictions and are not released by CMS and must not be released by states. The pricing data CMS receives is held in the strictest confidence, and must not be released by states. The pricing data CMS receives is held in the strictest confidence and maintained only on CMS's master files. CMS sends URAs to states, but actual pricing data goes no farther than CMS.

(Roxane SOF, Tab 142A, at D2.)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 106 accurately quotes from Tab 142A of Roxane's Statement of Facts. Defendants dispute that the quoted portion of Tab 142A of Roxane's Statement of Facts constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100 and 102 above.

107. In a letter to the State of Texas dated May 3, 2004, CMS stated:

> You ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for reimbursement. You are correct. In light of the confidentiality provisions of Section l927(b)(3)(D) of the Social Security Act, drug pricing information disclosed by manufacturers pursuant to the drug rebate provisions is confidential and shall not be disclosed by either the Secretary or the State.

(Henderson Common Exhibit 31)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 107 accurately quotes from Henderson Common Exhibit 31. Defendants dispute that the quoted portion of Henderson Common Exhibit 31 constitutes a correct or reasonable interpretation of

the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100 and 102 above. Defendants further state that, in 2001, the OIG recommended that CMS use AMPs to create "estimated acquisition costs" ("EACs") to be used to calculate Medicaid reimbursement or, in the alternative, provide AMPs directly to state Medicaid programs so that the state Medicaid programs could use AMPs to calculate EACs. (*See* Reid Decl., Ex. 38, at 21-22.) The OIG further stated that using AMPs in this manner would not be inconsistent with the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D). (*See id*. at 22.) Furthermore, regardless of CMS's position regarding the use of AMPs as a reimbursement basis, Texas requires manufacturers to report AMPs to it directly. (See response to ¶ 100, *supra*.)

108. In a statement submitted to the Subcommittee on Health Care of the Senate Finance Committee on or about March 14, 2002, CMS Administrator Thomas Scully stated, "We collect AMP data for Medicaid on one side of my agency. . . . But by statute we're not allowed to share that with the Medicare side of the agency. It's proprietary data just for the purpose of the Medicaid program the law that created it prohibited us from using AMP for Medicare AMP provides a pretty good source of data, but by statute it is limited to use for the Medicaid program and the Medicare side of my agency doesn't have access to it by law." "Reimbursement and Access to Prescription Drugs Under Medicare Part B," 107th Cong. 16, Hearing Before the Subcomm. on Health Care of the S. Finance Comm. (March 14, 2002) (statement of Thomas A. Scully), 2002 WL 399357 at *18-19.

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 108 accurately quotes the referenced Congressional testimony. Defendants dispute that the quoted portion of the testimony constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100 and 102 above. Defendants further state that, in his testimony in this action, Mr. Scully acknowledged that one could easily compare AMPs to AWPs and calculate spreads between the two:

> Q. Okay. So, CMS employees, to nail this down, could sit down and take a look at the AMP for Albuterol, and compare that to the AWP for Albuterol, and calculate precisely the spread between those two points; right?
>
> MR. NEAL: I'll object to the form.
>
> MR. RIKLIN: Objection to form.
>
> A. I believe that's true, yes.
>
> Q. And that data existed within CMS Medicaid during the entire time that Dey's products were reimbursed under Medicaid; right?
>
> MR. NEAL: Objection as to form.
>
> A. I don't know what year we started collecting AMP, but whenever they started collecting AMP, yes.
>
> (Reid Decl., Ex. 33, at 619:4-18).

109. Larry Reed, Technical Director in the Division of Pharmacy, CMS, testified regarding AMP information submitted by manufacturers, stating, "The information that we would get from the manufacturers would not be part of the reimbursement system. The information that we get from the manufacturers would be part of the rebate program, the AMP data, the best price data." (Henderson Common Exhibit 32 (10/2/08 Reed Dep.), at 1094:4-9)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 109 accurately quotes Mr. Reed's deposition testimony. Defendants dispute that the quoted portion of the testimony is based upon or reflects a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100 and 102 above.

110. Responsible officials at CMS testified that understood AMPs were confidential, and could only be used for purposes of the Rebate Program. *See, e.g.* (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 282:20 - 283:4; Henderson Common Exhibit 34 (9/27/2007 Reed Dep.), at 352: 14 - 353:11 ; Henderson Common Exhibit 35 (6/2 1/2007 Vladeck Dep.), at 457: 19 - 460:20, 464:7 - 464: 19, 584:21 - 586:4; Henderson Common Exhibit 36 (2/27/2007 Duzor Dep.), at 368:14 - 369:10)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 110 accurately refers to the referenced testimony. Defendants dispute that the cited testimony constitutes a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. §

1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100, 102, and 107 above. Defendants further state that, regardless of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D), state Medicaid programs had access to AMPs and could compare them to their reimbursement payments. For instance, Bruce Vladeck, the Administrator of HCFA from May 1993 to September 1997, testified:

> Q: So as far as you know, people within HCFA shared AMP data with state Medicaid agencies?
>
> A: That was my understanding.
>
> * * *
>
> Q: So it was entirely possible -- it was entirely possible for the heads of a state Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to what they were reimbursing for those drugs. That was entirely possible. Right?
>
> * * *
>
> A: It's -- I don't know any reason why it wouldn't be possible.

(Reid Decl., Ex. 35, at 461:12-15, 463:19-464:06.) Likewise, Thomas Scully, the Administrator of CMS from May 2001 to December 2003, testified:

> Q: Did you ever tell any state that they should calculate their reimbursement methodology for Medicaid taking into account AMP data?
>
> A: No.
>
> Q: Why not?
>
> A: States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.

(Reid Decl., Ex. 33, at 627:13-20.) Deirdre Duzor, the CMS Director of the Pharmacy Division for the Medicaid program, testified that it would be relatively simple to derive the AMP from a URA for a generic drug:

> Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
>
> * * *

A: Yes. The AMPs have been fairly transparent for generic drugs.

(Reid Decl., Ex. 37, at 679:12-17.)

111. AMPs were not utilized in the calculation of Federal Upper Limits, as AMPs were not listed in "published compendia." 42 C.F.R. § 447.332(a)(l)(ii); Henderson Common Exhibit 40 (Declaration of Susan Gaston), ¶ 6 [Exhibits omitted]. Persons responsible for setting FULs at CMS did not use AMPs, as AMPS are not listed in "published compendia." *Id*.; Henderson Common Exhibit 37 (3/19/2008 Gaston Dep.), at 528:4 - 529:1)

DEFENDANTS' RESPONSE: Defendants do not dispute that AMPs were not utilized in the calculation of Federal Upper Limits ("FULs"). To the extent the United States asserts that AMPs could not be used to calculate FULs because of the provisions of 42 C.F.R. § 447.332(a)(1)(ii), the United States does not state undisputed or material facts. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that this assertion could be read to state undisputed or material facts, they are disputed. Defendants state that, regardless of the provisions of 42 C.F.R. § 447.332(a)(1)(ii), there is nothing that would legally prohibit CMS from incorporating AMPs into Medicaid reimbursement methodologies or allowing states to do the same. Defendants incorporate herein their responses to paragraphs 100, 102, and 107 above.

112. AMPs were on occasion provided to HHS, Office of the Inspector General, in furtherance of the OIG's mission to conduct audits and investigations, and to prevent and detect waste, fraud and abuse in the agency's programs and operations. 5 U.S.C. app. 3 §§ 2, 4, 8G (1988). However, responsible officials at OIG testified that they understood AMPs were confidential. (Henderson Common Exhibit 38 (2/6/2008 Vito Dep.), at 1196:10 - 1196:19) OIG and other governmental reports regularly referred to AMPs as confidential. Roxane SOF, Tab 91, at 20, Box 2 ("the average manufacturer price (AMP), used to calculate the Medicaid rebate, is not public information"); Roxane SOF, Tab 146, p.3 (Section 1927(b)(3)D) of the Social Security Act requires that, subject to certain exceptions, AMPs reported to CMS not be publicly disclosed)

DEFENDANTS' RESPONSE: Defendants do not dispute that AMPs were provided to the United States Department of Health and Human Services, Office of Inspector General. Defendants do not dispute that paragraph 112 correctly describes the cited deposition testimony and documents. Defendants dispute that the cited testimony and documents are based upon or reflect a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100 and 102 above.

113. CMS did not instruct states to use AMPs for reimbursement. (Henderson Common Exhibit 33 (9/26/2007 Reed Dep.), at 281:16-22)

DEFENDANTS' RESPONSE: Admitted.

114. State Medicaid officials have testified that they understood that AMPs were confidential, and that they could not use AMP information in setting reimbursement rates. (Henderson Common Exhibit 19 (12/10/2008 Bridges Dep. (Arkansas)), p. 70:5 -72:22; Henderson Common Exhibit 43 (12/3/2008 Gorospe Dep. (California)), at 283:8 - 284:21; Henderson Common Exhibit 11 (12/15/2008 Dubberly Dep. (Georgia)), at 83:20 - 86: 18; Henderson Common Exhibit 12 (11/18/2008 Parker Dep. (Illinois)), at 72:2 -74:8; Henderson Common Exhibit 21 (10/28/2008 Farrand Dep. (New Hampshire)), at 287:1 - 293: 17; Henderson Common Exhibit 14 (12/2/2008 Vaccaro Dep. (New Jersey)), at 77:1 - 77:16, 102:18 - 103:19; Henderson Common Exhibit 16 (10/21/2008 Weeks Dep. (North Carolina)), at 1 12:8 - 113:0; Henderson Common Exhibit 17 (12/15/2008 Rugg Dep. (Vermont)), at 373:1 - 373 :20)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 114 accurately describes the cited testimony. Defendants dispute that the cited testimony is based upon or reflects a correct or reasonable interpretation of the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D) and incorporate herein their responses to paragraphs 100, 102, and 107 above. Furthermore, regardless of whether state Medicaid officials believe that they can use AMPs to calculate reimbursement payments, states are free to gather AMPs directly from manufacturers. (*See* response to ¶ 100, *supra*.) Texas, California, Maine, and Vermont require drug manufacturers to report AMPs directly to their respective state Medicaid programs. (*See id*.)

115. In a 2001 report, the OIG discussed the confidentiality of the AMPs as follows:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(Reid Decl., Ex. 38, at 22.)

DEFENDANTS' RESPONSE: Admitted.

116. Dr. Duggan, the United States damages expert, relied upon multiple sources of Medicaid data. One category is data that was collected directly from the states in connection with this litigation. The other source was data was collected by the CMS directly from the states in connection with CMS ' administration of the Medicaid program. The state data in CMS' possession is of two types. One is known as the State Drug Utilization Data (SDUD) The other category includes three similar types of data known as the Medicaid Analytic Extract (MAX) data, the State Medicaid Research Files (SMRF) and the Medicaid Statistical Information System (MSIS). This data is similar and is generally referred to together as SMRF/MAX or SMRF/MAX/MSIS. The combination of the datasets provided Dr. Duggan with claims data from all 50 states. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶12-16.)

DEFENDANTS' RESPONSE: Defendants dispute paragraph 116. Defendants dispute that combination of the datasets relied on by the United States' purported expert, Dr. Duggan, provided Dr. Duggan with "claims data" from all 50 states. As admitted by the United States, the SDUD is aggregate data and does not provide detail for each individual claim. (Henderson

Common Decl., Ex. 41 ¶ 16.) Dr. Duggan only used Medicaid data collected directly from the states in his calculations for 10 states for Abbott, 14 states for Dey, and 16 states for Roxane. (*Id*. ¶ 17.) Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only on his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

Defendants do not dispute that the United States' purported expert, Dr. Duggan, relied on (1) Medicaid data collected directly from the states, (2) SDUD, and (3) SMRF/MAX data.

117. For various reasons, including need, timing, and resources, Dr. Duggan did not perform a claim by claim analysis of all of the data collected from the individual states. However, Dr. Duggan did use the data from the additional states in other ways, for example, to help evaluate which were the best states to include in the claim by claim analysis, and to help validate the SMRF/MAX/MSIS/SDUD data. (Henderson Common Exhibit 4 1 (Duggan Decl.), ¶ 17)

DEFENDANTS' RESPONSE: Defendants dispute the assertion that Dr. Duggan did not "need" to conduct such a review. This assertion is a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that this portion of paragraph 117 could be read to state an undisputed or material fact, it is disputed. In order to obtain accurate estimates, Dr. Duggan should have analyzed the complete state claims data. For example, a review of Dr. Duggan's extrapolation in the Dey case demonstrates that in instances where he extrapolated to SDUD and SMRF/MAX data, he overstated his damages estimates by over 20%. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.)

Defendants further dispute paragraph 117 because Dr. Duggan did not have state claims data for all states. In cases where he did not have data collected from individual states, he could not have used it to help validate the SMRF/MAX/MSIS/SDUD data as implied in paragraph 117.

Defendants do not dispute that Dr. Duggan did not perform a claim by claim analysis of all of the data collected from the individual states.

118. For Dr. Duggan's Medicaid analyses, he utilized claims data obtained directly from state Medicaid agencies for 10 states in Dr. Duggan's Abbott analysis, 14 states for Dr. Duggan's Dey analysis and 16 states in Dr. Duggan's Roxane analysis. The data from these states accounted for between 63 and 68 percent of all claims for the defendants Complaint products. The remainder of Dr. Duggan's analysis relied upon the data collected from the states by CMS. (Henderson Common Exhibit 41 (Duggan Decl.), ¶17)

DEFENDANTS' RESPONSE: Defendants dispute paragraph 118. Contrary to the statement in paragraph 118, the state claims data from these 10, 14, and 16 states does not account for between 63 and 68 % of all claims for the Defendants' Complaint products. Rather, when the aggregate SDUD and the SMRF/MAX data is subtracted, the state claims data only covers less than 55% of the claims. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 2.) Defendants do not dispute that Dr. Duggan only utilized state claims data for 10 states in Dr. Duggan's Abbott analysis, 14 states in Dr. Duggan's Dey analysis and 16 states in Dr. Duggan's Roxane analysis. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only on his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

119. The SDUD and SMRF/MAX data pertained to varying time periods for all 50 states plus the District of Columbia, and overlapped substantially with each other and with the data obtained directly from the states. The overlap in the data sets allowed Dr. Duggan to validate the accuracy of each data set through a review and comparison of each so that only data determined to be reliable was utilized. Dr. Duggan found no material variations between the datasets. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 18)

DEFENDANTS' RESPONSE: Defendants dispute paragraph 119. Dr. Duggan did not have access to multiple sources of data for all states and time frames, and therefore was not able to validate the accuracy of each data set for each state and time frame. For example, Dr. Duggan

admits that he was forced to use three types of data in order to perform his calculations for the 10, 14, and 16 states he focuses on. (US-SOF ¶¶ 150-152.) Defendants dispute the implication that there are no "material variations between the datasets." Dr. Duggan's comparison of the two data sets shows significantly greater variations for those states with lower Medicaid spending – which are generally the states for which he uses the data to compute his differences. In the Abbott litigation, Dr. Duggan provided the following testimony:

> Q. How about for the states with relatively low Medicaid spending. Is there a close correspondence in that data?
>
> A. There are more cases where there are discrepancies so most strikingly -- at least going in descending order down the table – would be Mississippi, where -- in which in the -- at the SDU data, looks like about $940,000. And in the MAX data, about 1.4 million. But if I recall having drilled down on that issue, that reflected one of the three years.
>
> BY MR. TORBORG:
>
> Q. Yes. It says Mississippi, there is only eight quarters there.
>
> A. That's correct.
>
> Q. Whereas you got 12 quarters in the, in the MAX data which help explain why the MAX data would be higher, right?
>
> A. That's correct
>
> Q. And now let's take a look at Colorado, three down. You've got roughly 760,000 in the SDUD data for 11 quarters, right?
>
> A. Uh-huh.
>
> Q. But then you've got about 1.1 million for 12 quarters in the MAX data, right?
>
> A. Correct.
>
> Q. There is a higher degree of variability there, right?
>
> A. That's correct.

Q. And if we look at Maryland, the SDUD data we have the same number of quarters, correct?

A. Correct.

Q. But the MAX data is 43.6 percent more, right?

A. Correct.

Q. Similarly for South Carolina, we have the same number of quarters, but the MAX data has 39 percent higher expenditures, right?

A. Correct.

Q. And if we look at Delaware, same number of quarters, that's toward the bottom, same number of quarters, but Delaware's spending is 65 percent higher in the MAX data, right?

A. Correct.

Q. So would it be fair to say that there is less heterogeneity in the states with lower Medicaid spending, right?

MR. LAVINE: Object to form.

THE WITNESS: I'm sorry. Could you repeat that? I think you flipped it but – there is less -- so I don't agree with what you said. Maybe you should –

BY MR. TORBORG:

Okay. There is more variability -- there is not as close a correspondence between the two data sets for the states with relatively low Medicaid spending?

MR. LAVINE: Object to form.

THE WITNESS: So for -- on average, that is true. But having drilled down on that issue, in many of these cases, it was often driven by incomplete SDU data. So even if it had some utilization, so for example, we talked a bit about Indiana where having drilled down on it, it has the same number of quarters in the two data sets, but there is still this disparity that exists. And having drilled down on it, if I recall, the SDU data was very low in that time period, like for a couple of quarters was peculiarly low. So with the -- so it is typically, you know, there are exceptions, like Tennessee, for

example, as you can see. But typically, it is the incomplete SDU data.

BY MR. TORBORG: Q. For -- take Colorado, for example. We looked at that one earlier?

A. Yes.

Q. Are you aware of any facts that the SDUD data is incomplete for that state, but for the one quarter you're missing?

A. No. This would be a -- I don't recall. It seems plausible, but I don't recall.

Q. Same answer for Maryland?

MR. LAVINE: Object to form.

THE WITNESS: Correct. I just don't 1 recall. And at some point, if we could take a bathroom break, that would be great.

* * *

Q. This is a table where you compare the amounts paid in the SDUD and SMRF data, this time for the period 1996 through 1998, correct?

A. Yes. That's right.

Q. And I take it you do that comparison for the same comparison that you -- the same reason that you did the '99 to 2001 comparison, right?

A. Correct.

Q. And you again note on page 28 of your report that there is a close correspondence in the data for those states with relatively high Medicaid spending, right?

A. Right.

Q. And then if you look at some of the states toward the bottom of the chart, these would be the states with relatively lower spending, right?

A. Correct.

Q. And you observed that the correspondence in the data is not as close for the states with relatively low spending, right?

> MR. LAVINE: Object to form.
>
> THE WITNESS: On average, I would say that's true. If we looked at, for example, Montana on down the line, the correspondence there is not as great as above.

(*See* Reid Common Decl., Ex. 12, at 707:13-17-711:14, 712:2-713:5.) As admitted by the Government, the SDUD is aggregate data and does not provide detail for each individual claim. (Henderson Common Decl., Ex. 41 ¶ 16.) This is a material difference because the SDUD does not allow the user to determine the payment basis for any claim.

Defendants further dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined 16 states' claims data and found that Dr. Duggan's calculations resulted in damage estimates that were 20% higher than if he had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Defendants do not dispute that the remainder of paragraph 119 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology.

120. Dr. Duggan never calculated any damages except where he had data that was directly based upon claims submitted to the state Medicaid programs which he had evaluated for reliability and concluded was reliable. In order to further improve upon the reliability of his results, Dr. Duggan performed various reviews. For example, he checked each claim contained in the data acquired directly from the states to verify its accuracy by seeing if he could replicate the amount paid. Data that was found to not match a state's methodology, or that was otherwise questionable was not used in Dr. Duggan's analysis. As a result, Dr. Duggan discarded large amounts of data that likely would have increased the calculated damages. (Henderson Common Exhibit 41 (Duggan Decl.), ¶19)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 120. Rather, the United States provides expert opinion and a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 120 could be read to state undisputed or

material facts, they are disputed. Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Defendants do not dispute that the remainder of paragraph 120 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. (*See also* response to ¶ 119, *supra*.)

121. For his Medicare Damages analysis, Dr. Duggan reviewed a complete set of Medicare J-code billing data, obtained directly from CMS. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 21)

DEFENDANTS' RESPONSE: Defendants do not dispute paragraph 121.

122. Dr. Duggan analyzed the J-code data separately for the durable medical equipment (DME) claims and for the Medicare Part B claims which generally represent drugs administered incident to the care of a physician. The vast majority of DME claims were processed by a total of four DME carriers at any one time. The DME carriers are called Durable Medical Equipment Regional Carriers or "DMERCs". (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 21)

DEFENDANTS' RESPONSE: Defendants do not dispute paragraph 122.

123. The Part B claims were processed by a greater number of carriers. The individual Part B carriers are identified by a total of 92 different codes, though in many cases the same carrier has multiple codes. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 21)

DEFENDANTS' RESPONSE: Defendants do not dispute paragraph 123.

124. The payment amounts for each HCPCS J-code are determined by each DME and Part B insurance carrier *(e.g.* Palmetto) in accordance with instructions from CMS with the typical carrier using the median AWP of the NDCs included in the

carrier's array as the per-unit allowed amount, with this changing to 95 percent of the median on January 1, 1998. The particular NDCs that are included in an array vary across carriers and can vary within the same carrier over time. Carriers sometimes shared arrays, or the resulting calculations, and did not always prepare new arrays if there were no changes to the prices. However, a complete set of the arrays used by every carrier to select the medians for each J-code for each time period was not available for Dr. Duggan's use. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 22)

DEFENDANTS' RESPONSE: Defendants dispute the first sentence of paragraph 124. From 1992 to 1997, the Medicare ingredient reimbursement formula was the lower of (1) the billed charge from the provider, or (2) the lower of the Estimated Acquisition Cost "EAC" or the median AWP of all of the generic forms of the products in the relevant code. (Dey SOF ¶ 175.) According to the Medicare regulations, EAC was to be based on surveys of actual invoice prices paid by providers. (Dey SOF ¶ 176.) In practice, the EAC component of Medicare Part B drug reimbursement allowable was never utilized. (*Id.*) In addition to the ingredient cost component, CIGNA and the other carriers would reimburse a dispensing fee for covered drugs.

Defendants do not dispute that the particular NDCs that are included in an array vary across carriers and can vary within the same carrier over time. DMERCs and carriers did not always choose to include the same drugs in their arrays. For example, Carolyn Helton of CIGNA testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Reid Decl., Ex. 153, at 151:7-17.) Defendants dispute any contention that the Medicare carriers consistently followed statutory mandates or regulations and guidance from CMS as it is contradicted by the factual record in this case. (*See also* Roxane SOF ¶¶ 163-224; Dey Resp. to US-Dey-SOF ¶ 205.)

125. There are three parts to Dr. Duggan's analysis of the Medicare claims. First, he reviewed the claims processed by Medicare under the DME benefit. These DME claims were processed by the DMERCs. Dr. Duggan has array information that applies to more than 90 percent of the claims for these DME claims and, as he detailed in his expert report, he dropped those claims for which he was unable to replicate the allowed amount from the claim from the array documents. There was

no need to extrapolate in connection with the DME claims. (Henderson Common Exhibit 41 (Duggan Decl.) ¶ 23)

DEFENDANTS' RESPONSE: Disputed. Dr. Duggan's calculations themselves are the best evidence of Dr. Duggan's methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Further, Defendants dispute the statement that "[t]here was no need to extrapolate in connection with DME claims." Dr. Duggan did extrapolate to compute some of his differences for DME claims. Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

126. Second, Dr. Duggan reviewed the claims processed by regular Medicare Part B carriers in situations where he had at least some of the arrays. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 24)

DEFENDANTS' RESPONSE: Defendants do not dispute the description of Dr. Duggan's analysis in paragraph 126 but state that the calculations themselves are the best evidence of Dr. Duggan's methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

127. Third, Dr. Duggan reviewed claims processed by regular Medicare Part B carriers for which he did not have the arrays. He performed separate damage calculations for each. The second and third steps were only necessary for his analysis of the Abbott claims. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 24)

DEFENDANTS' RESPONSE: Disputed. Dr. Duggan's e calculations themselves are the best evidence of Dr. Duggan's methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper

foundation. Defendants dispute the statement that Dr. Duggan "performed separate damage calculations for each. While Dr. Duggan listed separate difference computations for those carriers for which he did not have arrays, he did not perform separate calculations for those carriers. Rather, he simply applied difference ratios generated from his analysis where he had arrays to expenditures for carriers for which he did not have arrays.

128. There were several steps to Dr. Duggan's actual damage calculations. The first step was to calculate the average selling price of the defendants' products using the defendants' own transaction data. (Henderson Common Exhibit 41 (Duggan Decl.), ¶29-36) He then used the results of that analysis to determine the amounts that would have been paid by Medicare and Medicaid in reliance upon those transaction based prices. (Id., ¶ 25)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 128. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 128 could be read to state undisputed or material facts, they are disputed. Furthermore, Defendants dispute that the amounts calculated by Dr. Duggan are the amounts that would have been paid by Medicare and Medicaid in reliance upon those transaction based prices. The United States has provided no evidence that Dr. Duggan's difference calculation is based on what Medicaid would have reimbursed. Dr. Duggan himself admits that his calculation is based upon the assumption for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (Reid Common Decl., Ex. 5, at 345:14-16; Reid Common Decl., Ex. 6, at 420:13-16.) But, the United States has provided no evidence to support this assumption. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants

dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

129. Dr. Duggan directly calculated Medicaid damages on a claim by claim basis using data acquired directly from the ten states for Abbott, fourteen states for Dey and sixteen states for Roxane representing 63% to 68% of the total dollars paid on the defendants' drugs. He extrapolated from that amount to calculate a relatively modest amount of additional damages for those same ten, fourteen or sixteen states. Dr. Duggan also extrapolated from that amount to the other states plus the District of Columbia to calculate additional damages. (Henderson Common Exhibit 41 (Duggan Decl.) ¶¶ 26, 37-38)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 129. Rather, the United States provides legal conclusion; therefore, no response should be required. To the extent that paragraph 129 could be read to state undisputed or material facts, they are disputed. Contrary to the paragraph 129, the state claims data from these 10, 14, and 16 states does not account for between 63 and 68% of all claims for the Defendants' Complaint products. Rather, when the aggregate SDUD and the SMRF/MAX data is subtracted, the state claims data only covers less than 55% of the claims. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 2.) Defendants dispute that Dr. Duggan has calculated "damages." Defendants dispute that Dr. Duggan has only extrapolated "relatively modest" amounts of "additional damages" for those states for which he had claims data. Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

Defendants do not dispute that Dr. Duggan only considered state level claims data for 10 states for Abbott, 14 states for Dey and 16 states for Roxane.

130. Dr. Duggan directly calculated Medicare damages on the DME claims where Dr. Duggan had 90% of the arrays for all three defendants. (Henderson Common Exhibit 41 (Duggan Decl.) ¶ 27)

DEFENDANTS' RESPONSE: Defendants do not dispute the description of Dr. Duggan's analysis in paragraph 130 but state that the calculations themselves are the best evidence of Dr. Duggan's methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

131. For Abbott, on the Part B claims where Dr. Duggan had some arrays he performed a calculation of damages. Dr. Duggan used that damage calculation as a basis for calculating damages associated with the other Part B carriers. (Henderson Common Exhibit 41 (Duggan Decl.), ¶28)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 131. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

132. The manner in which Dr. Duggan calculated damages for Medicare is straightforward. If, for example, defendants had one product in a particular carrier's array for one of the HCPCS codes listed in the Complaint, then that price would be substituted in the array to see if the median price from that array would change. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 49)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 132. Rather, the United States provides expert opinion and a legal conclusion; therefore, no response should be required. To the extent that paragraph 132 could be read to state undisputed or material facts, they are disputed. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to

damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

The carriers had discretion in creating arrays and the United States has provided no evidence that the Medicare carriers would in fact choose to include Dr. Duggan's prices in their arrays. Defendants incorporate by reference their response to paragraph 132.

Defendants further dispute that Dr. Duggan's calculations are straightforward. For example, Dr. Duggan proposed four different "damages" models, in two of which Dr. Duggan improperly substitutes the price of more than one defendant in the same array. (*See* Dey Resp. to US-Dey-SOF ¶ 219; Roxane SOF ¶ 228.) Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dr. Duggan also selectively chose to correct certain DMERC errors while maintaining others in calculating his Medicare differences. (Roxane SOF ¶¶ 225-52.) For example, in two of his four damages models, Dr. Duggan depends on the DMERCs' inconsistent classification of Novaplus ipratropium bromide in calculating differences for Roxane. (Roxane SOF ¶¶ 237-42.)

133. Dr. Duggan repeated this exercise for all of the arrays located from the carriers, and this allowed me to estimate how Medicare spending would have changed if alternative prices had been used for defendants' products' AWPs. More specifically, if using 125 percent of defendant' s average transaction prices as the AWP for defendants' NDCs would reduce the median, Dr. Duggan replaced the per-package price used by the carriers in adjudicating the claim with the revised median. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 53)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 133. Rather, the United States provides expert opinion and a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 133 could be read to state undisputed or

material facts, they are disputed. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

The carriers had discretion in creating arrays and the United States has provided no evidence that the Medicare carriers would in fact choose to include Dr. Duggan's prices in their arrays. Defendants incorporate by reference their response to paragraph 133.

The United States has provided no evidence that Dr. Duggan's difference calculation is based on what Medicare would have reimbursed. Dr. Duggan himself admits that his calculation is based upon the assumption for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (Reid Common Decl., Ex. 5, at 345:14-16; Reid Common Decl., Ex. 6, at 420:13-16.) But, the United States has provided no evidence to support this assumption.

134. Dr. Duggan repeated the foregoing process for each of the carriers for each of the defendants. It is important to emphasize that the dollar figure for the damages does not account for the effect on the co-payments of Medicare recipients. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 54)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 134. Rather, the United States provides expert opinion, legal conclusion, and argument; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 134 could be read to state undisputed or material facts, they are disputed. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants

dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

The carriers had discretion in creating arrays and the United States has provided no evidence that the Medicare carriers would in fact choose to include Dr. Duggan's prices in their arrays.

The United States provides no factual basis to support why "that the dollar figure for damages [should] account for the effect on the co-payments of Medicare recipients," and has conducted no analysis of any such effect. Thus, this statement is unsupported by evidence and immaterial to any party's motion for summary judgment and should be disregarded. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006); Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005).

135. In the Abbott analysis, with respect to the Part B carriers, Dr. Duggan performed this analysis for Connecticut General, Wisconsin Physician Services, certain other Region 5 carriers that shared the arrays with Wisconsin Physician Services, Kentucky Administar, West Virginia Nationwide, other Metra Health and Florida Blue Shield. (During the latter several years of the study period, seven other carriers operating in CMS Region 5 — Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin — used the allowed amounts from the WPS arrays described above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 55)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 135 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants further state that the United States' statement that, "During the latter several years of the study period, seven other carriers operating in CMS Region 5 — Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin — used the allowed

amounts from the WPS arrays described above," is not specific enough (namely, what is meant by "latter years") to warrant a response. Defendants further state that the United States has not supported this statement with competent or admissible evidence. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

136. Extrapolation is simply described as a way to estimate by projecting known data. Extrapolation is a tool used by economists even if complete and perfect data exists. This is the case because use of all data is often time consuming or prohibitive and unnecessary. There are acceptable methods of extrapolation and Dr. Duggan has used them in this case. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 56)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 136. Rather, the United States provides expert opinion and argument; therefore, no response should be required. To the extent that paragraph 136 could be read to state undisputed or material facts, they are disputed. Defendants dispute the assertion that the use of state claims data was prohibitive or unnecessary in this case. In order for Dr. Duggan to come up with a reliable estimate, he needed to use the state level claims data. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack

the proper foundation. Defendants dispute the implication that Dr. Duggan's extrapolation is reliable for the same reasons.

137. Dr. Duggan had various data sets for use. The fact that Dr. Duggan did not have state-produced claims data for some states did not mean Dr. Duggan did not have state claims data. As Dr. Duggan explained above, CMS had state claims data collected from earlier state productions in a form different than the individual claims data provided by the states during the litigation. In fact, if states were unable or unwilling to produce in litigation their individual claims data, Dr, Duggan believes he still could have performed a reasonable estimate of damages in this case from the state data collected by CMS. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 58)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 137. Rather, the United States provides expert opinion; therefore, no response should be required. To the extent that paragraph 137 could be read to state undisputed or material facts, they are disputed. Defendants dispute the statement that "The fact that Dr. Duggan did not have state-produced claims data for some states did not mean Dr. Duggan did not have state claims data." As admitted by the United States, one of the data sets used by Dr. Duggan, the SDUD, is aggregate data that does not include the payment basis information. Defendants further dispute the assertion that the use of state claims data was unnecessary in this case. In order for Dr. Duggan to come up with a reliable estimate, he needed to use the state level claims data. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use

the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants dispute the implication that Dr. Duggan's extrapolation is reliable for the same reasons.

138. Dr. Duggan's use of extrapolation — to a reasonable degree of economic certainty — arrived at a reasonable approximation of the damages, or difference between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicaid recipients during the relevant period, and (2) what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which defendants were transacting business had been reported by defendants. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 60)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 138. Rather, the United States provides expert opinion, argument, and a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 138 could be read to state undisputed or material facts, they are disputed. Defendants dispute that Dr. Duggan's calculations represent the difference between what the federal government reimbursed for certain products and "what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which defendants were transacting business had been reported by defendants." The United States has provided no evidence that Dr. Duggan's difference calculation is based on what Medicaid would have reimbursed. Dr. Duggan himself admits that his calculation is based upon the assumption for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (Reid Common Decl., Ex. 5, at 345:14-16; Reid Common Decl., Ex. 6, at 420:13-16.) But, the United States has provided no evidence to support this assumption.

Defendants dispute the United States' statement that Dr. Duggan's Medicaid "damage" calculations are reasonable. For example, Dey's expert examined state claims data for 16 states

and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants do not dispute that the remainder of paragraph 138 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

139. As Dr. Duggan describes in his declaration, not all states directly produced all of the claims data for all of the drug products at issue. As an supplement, Dr. Duggan used claims data that the states provided to CMS in connection with the normal operations of the Medicaid program, some of which was claims-level data and some of which was aggregated data. Aggregated data describes high-level data that is composed of a multitude or combination of other more individual data. The use of such aggregated data does not diminish the reliability or validity of the damages estimate Dr. Duggan calculated. As an economist, Dr. Duggan is trained in methods of using aggregated data when individual data is unavailable or prohibitive and unnecessary, all of which was true in this litigation. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 62)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 139. Rather, the United States provides expert opinion, argument, and a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam,* 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 139 could be read to state undisputed or material facts, they are disputed. Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted

in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

In order for Dr. Duggan to come up with a reliable estimate, he should have analyzed the complete claims data, as seen in the errors noted above. The United States failed to obtain and preserve such complete claims data. (*See* Defendants' spoliation motions, Dkts. 6097-8, 6253-5, 6110-11, and 6368.) Defendants further state that the aggregate data used by Dr. Duggan does not allow the user to determine the payment basis for any claim.

140. For the remainder of the states, Dr. Duggan used the information regarding the 10, 14 or 16 states as the basis for estimating the additional damages. The extrapolation from the 1 0, 14 or 1 6 states to the other states was reasonable for at least the following several reasons. First, Dr. Duggan extrapolated only to those periods for which he had claims data that he found to be reliable. Second, Dr. Duggan used data for more than one thousand combinations of NDC quarters when estimating the damages associated with the other states. Third, for 10, 14 or 16 states, Dr. Duggan ran his analysis on a claim by claim basis. His extrapolations were based on his detailed analysis of this large proportion of the overall claims (63% to 68% of the total paid for the defendants' Complaint NDCs) and his methodology allowed me to re-adjudicate each of those millions of claims. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 63-64)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 140. Rather, the United States provides expert opinion, argument, and a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F.

Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 140 could be read to state undisputed or material facts, they are disputed. The United States failed to obtain and preserve such complete claims data. (*See* Defendants' spoliation motions, Dkts. 6097-8, 6253-5, 6110-11, and 6368.) Contrary to paragraph 140, the state claims data from these 10, 14, and 16 states does not account for between 63 and 68% of all claims for Defendants' Complaint products. Rather, when the aggregate SDUD and the SMRF/MAX data is subtracted, the state claims data only covers less than 55% of the claims. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 2.)

Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants do not dispute that the remainder of paragraph 140 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

141. As an economist, Dr. Duggan found this method to be more optimal than a traditional random sample, which would have been a review of a smaller fraction of those claims. Dr. Duggan also concluded his review was also a better method than sampling each NDC for each state for each year which could have required

thousands of separate samples with numerous sample claims in each sample; such an approach would have been near impossible and fewer claims would have been reviewed. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 64)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 141. Rather, the United States provides expert opinion, argument and legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 141 could be read to state undisputed or material facts, they are disputed. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only on his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Dr. Duggan's decision not to use traditional random sampling cannot justify the flaws in the methodology he did use. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations.

142. In many circumstances Dr. Duggan had detailed state data and other aggregated data from for the same time periods. When he compared data obtained directly from the states to this other data, he found the data from CMS was reliable because there were no significant variations between the two and because the total dollars and units generally matched. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ *65)*

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 142. Rather, the United States provides expert opinion, argument, and legal

conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 142 could be read to state undisputed or material facts, they are disputed. Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants also dispute Dr. Duggan's conclusion that the CMS data was reliable, because he was not able to perform checks on the aggregate data when he did not have the state level data. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

143. In addition, Dr. Duggan examined all of the data which he relied upon to assess its quality. For example, Dr. Duggan reviewed every claim in the data collected from the states to confirm that he could replicate the amount paid. This was a detailed review. For example, Dr. Duggan's examination of the data provided by Indiana revealed it to be unreliable, and I therefore did not use it in Dr. Duggan's analysis. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 66)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 143. Rather, the United States provides expert opinion, argument, and legal conclusion; therefore, no response should be required. To the extent that paragraph 143 could be read to state undisputed or material facts, they are disputed. Defendants dispute the United

States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

144. Dr. Duggan had also claims data from over 30 states which covered at least part of the relevant time period, and he performed a general review of this data to confirm that it was consistent with his other findings. Dr. Duggan chose not to use all of the state data in his possession to perform detailed claim by claim calculations because it was prohibitive or duplicative and unnecessary. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 67) By focusing on the 10, 14 or 16 states, he was able to perform a higher quality review of the state claims data which served as the basis for the extrapolation. The state pharmacy reimbursement methodologies for the 10, 14 or 16 states were very similar to the state pharmacy reimbursement methodologies for the 40 states. *(Id.*, ¶ 68) The average amounts paid for each NDC by the 10, 14 or 16 states were very similar across the 10, 14 or 16 states. The average amounts paid for each NDC by the 10, 14 or 16 states were also very similar to the average amounts paid for each NDC by the other states. *(Id.*, ¶ 69)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 144. Rather, the United States provides argument and legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 144 could be read to state undisputed or material facts, they are disputed. Defendants dispute the statement that "the state pharmacy

reimbursement methodologies for the 10, 14 or 16 states were very similar to the state pharmacy reimbursement methodologies for the 40 states." This assertion ignores factors such as payment levels established by state MACs, for example.

Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants further dispute the assertion that claim by claim calculations were prohibitive or duplicative and unnecessary. As demonstrated by the review of Dr. Duggan's calculations, state level data was necessary in order to obtain more accurate calculations.

Defendants do not dispute that the remainder of paragraph 144 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

145. Dr. Duggan eliminated a substantial number of claims which did not precisely match the expected reimbursement and the damages on those claims were assumed to be zero even though it is likely that there were some damages associated with those claims. Dr. Duggan made numerous downward adjustments in the scope and magnitude of my extrapolations that would more than offset the magnitude of any differences between the 10, 14 or 16 states and the other states. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 70)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 145. Rather, the United States presents argument and legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 145 could be read to state undisputed or material facts, they are disputed. The United States exaggerates the magnitude of the claims that Dr. Duggan eliminated from his difference analysis, and neither it nor Dr. Duggan has made any showing that Dr. Duggan's "numerous downward adjustments in the scope and magnitude of my extrapolations that would more than offset the magnitude of any differences between the 10, 14 or 16 states and the other states." It is pure speculation. Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants dispute paragraph 145 as hearsay.

146. As Dr. Duggan calculated the damages in this case, he performed many different tests to confirm that the data was suitable for the purposes at hand. Thus, there were numerous checks done to confirm that each of the data sets was reliable and could be used in the manner that he used them. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 72)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 146. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 146 could be read to state undisputed or material facts, they are disputed. Dr. Duggan's various "checks" and "tests" did not result in reliable figures. Defendants further dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

147. Defendants and their experts posit that extrapolations can only be done in connection with routine random samples, or routine disproportionate random stratified samples of the type typically done when examining the claims of a single provider over the course of a single year. While the typical way to select a representative, non-biased sample is through randomization, a sample can still be representative and non-biased even if not selected through a random process. Dr. Duggan chose to focus on the largest states to obtain the maximum amount of precision As Dr Duggan explain in a rebuttal report, it is more important to the total value of the damages to be as accurate as possible for the state of Florida, than it is in the state of Vermont. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 73-74)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 147. Rather, the United States provides a legal conclusion and argument; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 147 could be read to state undisputed or

material facts, they are disputed. Dr. Duggan's decision not to use traditional random sampling cannot justify the flaws in the methodology he did use. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations.

Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

148. One quite simple, but significant component of the extrapolation that Dr. Duggan performed (as is true for any extrapolation) is that it is based on averages. Thus, assuming one has done the types of checks that Dr. Duggan has done, the variables that would tend to raise the damages figures are balanced by the variables that would tend to lower the damages figures. On average, of course, the number is reliable. A criticism based solely upon cherry picking examples of the variables that would tend to raise the damages figures without factoring in the variables that would tend to lower the damages figures is not reliable. Rather, such biased criticism suffers from the exact same type of flaw that the defense experts allege to be the supposed problem Dr. Duggan's analysis. A key difference is that his analysis considered both sides of the equation, whereas the defendant's experts appear to only or primarily consider the side of the equation that benefits defendants. There are numerous examples throughout Dr. Duggan's analysis of adjustments that reduce the amount of the damages that he have calculated, and those adjustments more than offset any of the alleged shortcomings leveled by the defendants. In addition, defense experts' criticisms are leveled without the benefit of any actual quantification of the supposed impact, so they are unhelpful. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 76)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 148. Rather, the United States provides argument and legal conclusion;

therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 148 could be read to state undisputed or material facts, they are disputed. Defendants dispute the United States' implication that Dr. Duggan's Medicaid "damage" calculations are reliable. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Neither the Government nor Dr. Duggan has done anything to support the statement that Dr. Duggan's "analysis of adjustments that reduce the amount of the damages that he [would] have calculated, and those adjustments would have more than offset any of the alleged shortcomings leveled by the defendants." It is pure speculation. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

149. In certain periods for each of these 10, 14 or 16 states, Dr. Duggan did not have complete state claims data collected directly from the states. However, that data was generally very complete. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 77)

DEFENDANTS' RESPONSE: Defendants do not dispute that Dr. Duggan did not have complete state claims data collected directly from the 10, 14, or 16 states he considered. Defendants dispute the second sentence of paragraph 149. In paragraphs 150-52, the Government admits that Dr. Duggan was missing between 17.9% and 6.5% of the total claims

for the 10, 14, or 16 states he examined. Defendants further dispute the statement that the data "was generally very complete" as an opinion rather than a material fact.

150. In Dr. Duggan's Abbott analysis, the data for the 10 states accounted for approximately 86.8 percent of the claims. Thus, Dr. Duggan used the SMRF/MAX/MSIS for 8.7 percent of the claims data from CMS and aggregate SDUD data from CMS for an additional 4.5 percent. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 78)

DEFENDANTS' RESPONSE: Defendants do not dispute that Dr. Duggan did not solely consider state level claims data in his analysis of the 10 states.

151. In Dr. Duggan's Dey analysis, the data for the 14 states accounted for approximately 82. 1 percent of the claims. Thus, Dr. Duggan used the SMRF/MAX/MSIS for 8.9 percent of the claims data from CMS and aggregate SDUD data from CMS for an additional 9.0 percent. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 79)

DEFENDANTS' RESPONSE: Defendants do not dispute that Dr. Duggan did not solely consider state level claims data in his analysis of the 14 states.

152. In Dr. Duggan's Roxane analysis, the data for the 16 states accounted for approximately 93.5 percent of the claims. Thus, Dr. Duggan used the SMRF/MAX/MSIS for 4.3 percent of the claims data from CMS and aggregate SDUD data from CMS for an additional 2.3 percent. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 80)

DEFENDANTS' RESPONSE: Defendants do not dispute that Dr. Duggan did not solely consider state level claims data in his analysis of the 16 states.

153. As a check on his approach on this issue, for each of the five largest states for which Dr. Duggan performed within-state extrapolations in the Abbott case (Florida, California, New Jersey, New York, and Kentucky) and for each of the states used in the Dey and Roxane cases, Dr. Duggan assumed for the sake of the calculation that the state Medicaid claims data started one year later than they actually did. He then utilized the SMRF/MAX/MSIS claims data if it was available and otherwise used the SDUD data to estimate the total value of the damages during these one-year periods. Dr. Duggan's findings indicate that the total value of the damages is actually substantially higher when he used the claims data collected directly from the states compared to when he extrapolated using the SDUD and SMRF/MAX/MSIS claims data. The fact that Dr. Duggan did not have complete state Medicaid claims data collected directly from the states for the entire eleven-year period for these states reduced rather than increased the total

> value of the damages. His extrapolation therefore inured to the benefit of the defendant. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 82)

DEFENDANTS' RESPONSE: Defendants dispute paragraph 153. It is not true that "The fact that Dr. Duggan did not have complete state Medicaid claims data collected directly from the states for the entire eleven-year period for these states reduced rather than increased the total value of the damages. His extrapolation therefore inured to the benefit of the defendant." For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Defendants do not dispute that the remainder of paragraph 153 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

> In connection with his extrapolation from the 10, 14 or 16 states to the other states, Dr. Duggan also performed various additional checks. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 83-85)

DEFENDANTS' RESPONSE: Defendants dispute this statement. Dr. Duggan could not perform "various additional checks" where he did not have additional state level data. Dr. Duggan's various "checks" did not result in reliable figures. For example, Dey's expert examined state claims data for 16 states and found that Dr. Duggan's calculations resulted in difference estimates that were 20% higher than if Dr. Duggan had used the state level claims data that was available to him. (*See* Reid Opp. Decl., Ex. 405 (Bradford 8/28/09 Decl.), ¶ 7, Figure 3.) Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert

Mark G. Duggan, Ph.D., Docket No. 6175, contains numerous specific examples demonstrating the unreliability of Dr. Duggan's extrapolations. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants further dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

154. Dr. Duggan used multiple sources of detailed information regarding Medicaid claims for the drugs at issue for those states to which he was extrapolating. Additionally, Dr. Duggan did not extrapolate to any state or time period in which he did not have any CMS data (claims information from the state or SDUD data). (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 86)

DEFENDANTS' RESPONSE: Defendants dispute paragraph 154. Dr. Duggan did not have "multiple sources of detailed information regarding Medicaid claims for the drugs at issue for those states to which he was extrapolating," and Dr. Duggan himself admits that in some cases where he did have state claims data for the extrapolated states, he did not use it. (*See* paragraph 117, *supra*.) Defendants also dispute that the claims data utilized by Dr. Duggan is "detailed." As admitted by the Government, the SDUD is aggregate data and does not provide detail for each individual claim. (Henderson Common Decl., Ex. 41 ¶ 16). Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

155. The algorithm Dr. Duggan used was very straightforward. He began his analysis of each of the other state's SMRF / MAX data by applying inclusion criteria analogous to those described above for the 10, 14 or 16 preceding states. For example, he dropped claims with a paid amount of zero or with a strictly positive third party payment amount. Dr. Duggan then aggregated the number of claims and total Medicaid spending for each state by NDC-quarter. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 89)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 155. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 155 could be read to state undisputed or material facts, they are disputed. Defendants dispute that "the algorithm Dr. Duggan used was very straightforward," among other deficiencies, since it lacked any reasonable foundation. Defendants do not dispute that the remainder of paragraph 155 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology.

156. Dr. Duggan then merged this claims data for each of the remaining states to a data set in which the unit of observation was the NDC-quarter and that was constructed using the 10, 14 or 16 states' Medicaid claims data described above. For each NDC-quarter, Dr. Duggan first calculated the average fraction of claims with a difference greater than zero across all 10, 14 or 16 states. Dr. Duggan also calculated the average value of the ratio of the difference to the amount of Medicaid spending on these claims. In calculating these averages, Dr. Duggan weighted each of the 10, 14 or 16 states that had data for that NDC-quarter equally, while states with no claims data for that NDC-quarter have a weight of zero. These averages then were used in his algorithm. Dr. Duggan followed a similar algorithm for the SDUD data. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 90)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 156 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

157. Dr. Duggan's use of extrapolation — to a reasonable degree of economic certainty — arrived at a reasonable approximation of the Medicare damages, or difference, between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicare recipients during the relevant period, and (2) what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which

defendants were transacting business had been reported by defendants. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 91)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 157. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 157 could be read to state undisputed or material facts, they are disputed. Defendants dispute that the figures calculated by Dr. Duggan represent "what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which defendants were transacting business had been reported by defendants." Dr. Duggan himself admits that his calculation is based upon the assumption for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (Reid Common Decl., Ex. 5, at 345:14-16; Reid Common Decl., Ex. 6, at 420:13-16.)

Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

158. For all three defendants, his analysis of the Medicare claims based upon the carriers and carrier periods with arrays was reasonable for at least the following reasons. First, all carriers were hired by CMS to perform the same job, received the same instructions from CMS, and used the same price source — Red Book. Second, for those arrays Dr. Duggan did use in my analysis, one of defendants' products was included in almost every case. Third, Dr. Duggan eliminated a substantial number of claims which did not precisely match the expected reimbursement, and he assumed the damages on those claims were zero even though it is likely that there were some damages associated with them. An assumption that there were no damages for the other carriers is more likely to be wrong by a larger margin than these results. Finally, Dr. Duggan analyzed carrier array practices and did not see any evidence from defense or otherwise that carriers used different approaches in cases where he had arrays than in cases

where he did not have arrays. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 92-93)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 158. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 158 could be read to state undisputed or material facts, they are disputed. First, the evidence demonstrates that even if all carriers were hired by CMS to perform the same job, received the same instructions from CMS, and used the same price source, they did not always choose to include the same drugs in their arrays.

Defendants dispute any contention that the Medicare carriers consistently followed statutory mandates or regulations and guidance from CMS is disputed and contradicted by the factual record in this case. For example, Carolyn Helton of CIGNA testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Reid Decl., Ex. 153, at 151:7-17.) She "generally did not select drugs with special sized packaging, or convenience items such as flip-top vials, carpu-jets, tubes, and others." (Henderson Common Decl., Ex. 3 ¶ 10; *see also* Roxane SOF ¶¶ 163-224; Dey Resp. to US-Dey-SOF ¶ 205.) In fact, the United States concedes (and submits evidence showing) that the DMERCs varied widely in the sources of Red Book they used, as well as their procedures, processes, and results. (Roxane SOF ¶¶ 164, 166, 170, 180, 221; US Resp. to Roxane SOF ¶¶ 164, 170; Roxane Reply in Support of SOF ¶¶ 164, 170.)

Second, Dr. Duggan admits that one of defendants' products was not always included in the arrays he considered. (Henderson Common Decl., Ex. 41 ¶¶ 92-93.)

Defendants also dispute the implication in paragraph 158 that Dr. Duggan's Medicare calculations were reasonable or reliable. Defendants do not dispute that the remainder of

paragraph 158 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

159. For Dr. Duggan's Abbott analysis, the extrapolation based upon the Part B carriers and carrier periods with arrays was reasonable for at least the following reasons. First, for the time periods where Dr. Duggan had arrays, the damages he calculated were in an amount equal to 28.5% of the total payments by Medicare on those drugs. Due to Dr. Duggan's various conservative adjustments in cases where he did not have the arrays, the damages were only 16.1% of the total payments. Second, in claims during time periods for which Dr. Duggan did not have arrays, the allowed amount is equal to the published price of an Abbott product over 1.3 million times, thereby demonstrating that an Abbott product had to have been in the array. Second, Dr. Duggan did not calculate damages regarding 7 of the 12 Complaint J-codes, which account for more than 11 percent of Medicare spending on Complaint J-codes. For the DME claims, Dr. Duggan restricted attention to just the J33 70 code, which reduced the difference he calculated below what it would have been if he had considered the other ten J-codes (especially J705 1) as well. (Henderson Common Exhibit 4 1 (Duggan Decl.), ¶ 94)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 159. Rather, the United States provides argument and legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam,* 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 159 could be read to state undisputed or material facts, they are disputed. For the reasons stated in Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, Dr. Duggan's extrapolations are neither reliable nor conservative. The fact that Dr. Duggan did not compute differences for certain Abbott Complaint J-Codes with minimal expenditures (for which there may be no differences) does not render his analysis of those J-

Codes he did analyze (which accounted for a vast majority of spending on the Abbott Complaint J-Codes) "conservative."

Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

160. For the DME carrier damages, Dr. Duggan had array information that applied to more than 90 percent of the claims during the time in which almost all of the claims were paid. As Dr. Duggan explained in his expert reports, he dropped those claims for which he was unable to replicate the allowed amount from the claim from the array documents. Thus, Dr. Duggan performed no extrapolation in connection with the DME claims. For Abbott , it is also important to note that the total damages Dr. Duggan calculated was conservative because he dropped DME claims for all of the several J-codes. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 95-96)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 160. Rather, the United States provides a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that paragraph 160 could be read to state undisputed or material facts, they are disputed. Defendants dispute that Dr. Duggan's Medicare extrapolation "was conservative." Far from conservative, Dr. Duggan calculated damages based on Roxane's Novaplus ipratropium bromide products despite admitting (and the Government conceding) that these products were rarely if ever reimbursed under Medicare Part B. (Roxane SOF ¶¶ 151-55 (undisputed), 242-44.) Defendants do not dispute that the remainder of paragraph 160 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of

Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

161. To calculate the damages in circumstances where the arrays were not available, Dr. Duggan used results from the carriers for which he had array information to conduct analyses analogous to those in the preceding sections for the remaining carriers. Before doing this, Dr. Duggan first considered the Medicare Part B claims for all carriers to determine whether the two groups were comparable. The data suggested that the amount paid per claim for each J-code, the pattern of spending over time, and the proportion of claims accounted for by each of the five J-codes is quite similar. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 97)

DEFENDANTS' RESPONSE: Defendants dispute that proportion of claims accounted for by each of the five J-codes is "quite similar." Defendants also dispute that the statement that "Dr. Duggan used results from the carriers for which he had array information to conduct analyses analogous to those in the preceding sections for the remaining carriers." The analysis that Dr. Duggan conducted for the remaining carriers is nothing at all like the analysis he conducted for those carriers for which he had array information. Defendants do not dispute that the remainder of paragraph 161 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

162. Dr Duggan also determined the frequency with which each of the two groups had an Abbott NDC's AWP (or 95 percent of its AWP) as the allowed amount per unit. Dr. Duggan did this to investigate whether other carriers used Abbott NDC's as frequently in their arrays during the time period of interest. For example, Dr.

> Duggan found that 24.41 percent of Medicare claims administered by CG and the other carriers described above had an Abbott AWP as the allowed amount during the 1995Q3 (the first quarter for which Dr. Duggan had arrays for multiple products) to 2001Q4 period. The corresponding fraction for all other carriers is 18.44 percent. Dr. Duggan adjusted my estimates for the remaining carriers to account for the fact that the Medicare claims data indicated they used Abbott NDCs somewhat less frequently than CIGNA and the other carriers above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 98)

DEFENDANTS' RESPONSE: Defendants do not dispute that paragraph 162 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175. (*See* response to ¶ 169, *infra*.)

163. To estimate the number of claims for these remaining carriers with a value of the difference that is greater than zero and the total value of the difference, Dr. Duggan used an algorithm analogous to others he used and described in detail in his expert reports. Specifically, for the total value of the difference, Dr. Duggan multiplied NDC-specific total Medicare spending by these carriers by the ratio of the difference to the total amount of Medicare spending for the carriers for this same NDC. Dr. Duggan then deflated this value to account for the fact that these other carriers less frequently had Abbott AWPs as their allowed amounts. Dr. Duggan considered the 1993Q1 to 200 1Q4 period for these remaining carriers (thus ignoring 1991 and 1992), and calculated the number of provider payments with at least one claim with a value of difference that exceeded zero as described for the other Medicare carriers above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 99-100)

DEFENDANTS' RESPONSE: Disputed. Dr. Duggan's analysis for Medicare was focused on J-Codes, not NDC codes. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the

significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further dispute the statement that "the value of the difference does not account for the effect on Medicare recipients' co-payment amounts" as the United States provides no factual basis to support why these amounts should be considered and has conducted no analysis of any such effect. (*See* response to ¶ 134, *supra*.) Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175. (*See* response to ¶ 169, *infra*.)

164. The total value of the difference was $ 15.708 million, which represents 16.7 percent of the total amount spent by these carriers. This is lower than the corresponding ratio of 22.9 percent from Table 43 in his report because he scaled down the difference as described above. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 101)

DEFENDANTS' RESPONSE: Disputed. Dr. Duggan's analysis for Medicare was focused on J-Codes, not NDCs. Defendants do not dispute that paragraph 164 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175. (*See* response to ¶ 169, *infra*.)

165. As above, the value of the difference does not account for the effect on Medicare recipients' co-payments amounts. Additionally, Dr. Duggan has excluded 6 of the 11 J-codes from consideration, with these six accounting for approximately 4.5 million carrier claims and 11.0 percent of spending for the remaining carriers. This latter adjustment served to reduce the total value of the difference below what it would be if Dr. Duggan considered all eleven J-codes in the Complaint. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 102)

DEFENDANTS' RESPONSE: Disputed. Neither Dr. Duggan nor the United states has provided any support for the statement that "[t]his latter adjustment served to reduce the total value of the difference below what it would be if Dr. Duggan considered all eleven J-codes in the Complaint." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

166. As indicated in Table 35 of his June 19, 2008 report, Dr. Duggan had array information for 21 of the 91 carriers listed. Of the 6.172 million claims for the 21 carriers for which Dr. Duggan did have some array information, Dr. Duggan had array information from carrier documents for 3.590 million (58.2 percent) of them. Because these carriers tended to be significantly larger than the average, they accounted for a disproportionate share (40 percent) of Medicare carrier claims for the five J-codes that he considered. This fraction is much greater than economists frequently have for analyses of government programs. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 103-104)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in paragraph 160. Rather, the United States provides argument and a legal conclusion; therefore, no response should be required. Defendants dispute the last sentence of paragraph 166 as hearsay. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

167. Dr. Duggan extrapolated back in time for additional claims. Before doing this, however, Dr. Duggan examined the claims data to check that there was some evidence that the carrier was using Abbott products in its arrays by checking

> whether an Abbott product's AWP is the allowed amount in some cases. When there was little evidence to suggest that Abbott products appeared in the AWP, Dr. Duggan dropped the claims from consideration, which led him to drop 590,000 (9.6 percent) of the claims for these 21 carriers. After dropping these claims, Dr. Duggan applied an extrapolation methodology for the Medicare carrier claims that was analogous to the one described above for the 10 Medicaid states. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 104-105)

DEFENDANTS' RESPONSE: Disputed. Defendants dispute the statement that "Dr. Duggan applied an extrapolation methodology for the Medicare carrier claims that was analogous to the one described above for the 10 Medicaid states." Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

168. As for the remaining 70 carriers, which accounted for 60 percent of Medicare carrier claims for the five J-codes that Dr. Duggan considered, Dr. Duggan applied an extrapolation methodology that was similar to the across-state one that I used for the Medicaid analyses. For more than 1.3 million claims for these 70 carriers, Dr. Duggan was certain that an Abbott product was included in the array because its AWP was the allowed amount and no other firm's product typically had that same AWP at the same time. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 106, 108)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in the second sentence of paragraph 168. Rather, the United States provides expert opinion and a legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that the second sentence of paragraph 168 could be read to state undisputed or material facts, they are disputed. Defendants

dispute the statement that "Dr. Duggan applied an extrapolation methodology that was similar to the across-state one that I used for the Medicaid analyses."

Dr. Duggan's own statement of certainty relies on the statement that "no other firm's product typically had that same AWP at the same time." However, Dr. Duggan does not account for exceptions to this practice. Defendants do not dispute that the second sentence of paragraph 168 summarizes Dr. Duggan's calculations, but state that Dr. Duggan's underlying data is the best evidence of his methodology. Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation. Defendants further state that Abbott has filed Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175.

169. Dr. Duggan's examination of the Medicare claims data for the two groups of carriers (the 21 and the 70) indicated that the amount paid per claim for each J-code, the pattern of spending over time, and the proportion of claims accounted for by each of the five J-codes was similar. However, Dr. Duggan' s analyses also indicated that the frequency with which the seventy carriers used Abbott products in their arrays appeared to be lower. More specifically, Dr. Duggan found that 24.4 percent of the claims administered by the 21 carriers had an Abbott AWP as the allowed amount versus just 18.4 percent of the claims paid by the remaining 70 carriers. Dr. Duggan therefore adjusted my estimates for these 70 carriers downward to account for this factor. Using an appropriate and transparent methodology to adjust my difference results for the 21 carriers to the remaining 70, Dr. Duggan found that the ratio of the difference to spending for the remaining 70 was substantially lower for this latter group. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 106, 109)

DEFENDANTS' RESPONSE: The United States does not state undisputed or material facts in the fifth sentence of paragraph 169. Rather, the United States provides argument and legal conclusion; therefore, no response should be required. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). To the extent that the fifth sentence of paragraph 169

could be read to state undisputed or material facts, they are disputed. For the reasons stated in Abbott's Motion *in Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., Docket No. 6175, Dr. Duggan's extrapolations are neither reliable nor conservative. As explained in Abbott's motion *in limine*, due to the variability in the carrier arrays for the Abbott Complaint J-Codes, and the fact that it is the mix of NDCs in the arrays that drives Dr. Duggan's "difference," Dr. Duggan's simple comparison of the amount of time that the two sets of carriers had allowed amounts matching an Abbott NDC is not a reliable methodology for extrapolating a difference.

Defendants dispute that Dr. Duggan has calculated "damages." Dr. Duggan's expert reports refer to "differences" as opposed to damages, and only in his rebuttal report did he ultimately use the term "damages." Defendants dispute the significance of Dr. Duggan's calculations as they are inaccurate and lack the proper foundation.

Dated: August 28, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on August 28, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid